EFFICACY REVIEW

PRODUCT:	Selontra Rodent Bait, 7969-GIE TC 411, 7969-GIG TC 412, 7969-GIU BASF Corporation 26 Davis Drive Research Triangle Park, NC 27709
DATE:	January 3, 2016
DP NUMBERs:	433637 433681 433659
DECISION NUMBERs:	516184 516185 516186
GLP:	Yes
CHEMICAL:	Cholecalciferol (0.075%)
EPA PC CODE:	202901
PURPOSE:	Review submitted data to determine if they support registration of 3 new rodenticide products containing the active ingredient cholecalciferol
MRIDs:	49667508 (house mouse "surplus" method, BASF) 49667509 (rat choice feeding test, BASF) 49667517 (rat study, Stillmeadow) 49667518 (mouse study, Stillmeadow) 49667519 (unwrapped bait, rat study, Stillmeadow) 49667520 (unwrapped bait, mouse study, Stillmeadow) 49667524 (rat study per Protocol 1.209, BASF) 49667525 (mouse study per Protocol 1.210, BASF) 49667526 ("considerations" report, BASF) 49667527 (rat field trial, Bates) 49667528 (mouse field trial, Bates) 49667529 (rat field trial, Bates) 49667530 (rat field trial, Bates) 49667531 (rat field trial, Bates) 49667532 (mouse field trial, Bates) 49667533 (mouse field trial, Bates) 49667534 (mouse field trial, Bates) 49667535 (mouse field trial, Bates) 49667536 (rat field trial, Bates) 49667537 (rat field trial, Klemann) 49667538 (mouse field trial, Riegel) 49925401 (house mouse "surplus" method, BASF) 47981701 (bait station – opening, refilling and reclosing)

47981702 (bait station – child resistance)
47981703 (bait station – weather resistance)
47981704 (bait station – dog resistance)
47793801 (bait station – child resistance)

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BACKGROUND:

The Agency received applications from BASF Corporation to register three new end-use rodenticide products containing the active ingredient, Cholecalciferol at 750 ppm (0.075%). The three proposed products are summarized in the table below.

EPA Reg. No.	Product Name	Product Type	Pest
7969-GIE	Selontra Rodent Bait	soft block place pack	house mice, Norway rats, roof rats
7969-GIG	TC 411	Tier I refillable bait staiton; soft block place pack	house mice
7969-GIU	TC 412	Tier III disposable bait station; soft block place pack	house mice

Each of the three products would contain the same rodenticide, a bait block described by BASF's cover letter dated 4/11/16 as "a ready-to-use soft block rodent bait (RB) enrobed in a perforated flavor-permeable wrapper" (i.e., a placepack). Data submitted with this application package indicate that each "soft block" weighs 20 grams. Products 7969-GIG and 7969-GIU are to be contained within Tier I and Tier III bait stations, respectively, which appear to be those currently used in ready-to-use bait-station products registered to another registrant (Reckitt Benckiser) under EPA Reg. Nos. 3282-102 and 3282-97, respectively. These Reckitt products include bait stations which are refillable (3282-102) and single-use (3282-97), and thus at face value appear to jibe with what BASF is proposing in terms of labeling for 7969-GIG and 7969-GIU, respectively. However, the proposed marketing claims seem to indicate that a new station design is to be used (e.g., "new bait station"). If this is the case, BASF will be required to submit new data to support claims of tamper-resistance against children and, if the station is refillable and claimed to qualify as a Tier-I unit (7969-GIG), tamper-resistance data for dogs and for opening and refilling for the station. Additionally, if it is determined that the BASF's block differs from that used by Reckitt in the cited tamper-resistance studies in any way that might adversely affect whether the bait remains within the station, BASF will be required to conduct new studies to support the claims of tamper-resistance proposed for these two products.

The labeling submitted for Selontra Rodent Bait (7969-GIE) and routed for this review does not indicate an entry for "NET WEIGHT:". However, the 2008 Risk Mitigation Decision for Ten Rodenticides (RMD) states that packages of cholecalciferol products registered for the uses proposed for 7969-GIE must contain a minimum of 4 pounds of bait. Proposed uses for this product include use "Inside and within 100 feet of buildings or inside or transport vehicles (aircraft, ships, trains, and trucks) and for all burrow baiting." Although the product label bears text similar to that on many currently registered EPA products, some of the proposed language will require revision if 7969-GIE is to be registered (e.g., EPA does not currently permit burrow baiting use for block or placepack/paste formulations). More discussion of label language is provided at the end of this review.

The pending labels for TC 411 (7969-GIG) and TC 412 (7969-GIU) bear language on the front panel related to the tamper-resistance tiers proposed for these ready-to-use bait-station products. As 7969-GIG is to be marketed as a "consumer use" product, its proposed label includes language related to controlling house mice in and within 50 feet of homes. The label for 7969-GIU is only labeled for indoor use, with proposed label text related to its being a tier III bait station product. Much of the language is *similar to*, but not fully consistent with the relevant text set forth in EPA's RMD. Similarly to 7969-GIU, the packaging size is not indicated on either of the the labels proposed for these products which, presumably are intended for the "consumer" market, for which the RMD sets an upper limit of 1 pound of bait per retail package.[1] Clearly, the labels for all 3 products would have to be revised in order to make them acceptable for EPA registration.

BASF has submitted reports of a very large number of studies in support the proposed registrations of these three products. Many of these reports were routed for efficacy review. It appears that with the exception of the data specific to bait stations, all three of these products are to share the same efficacy data set. Cholecalciferol is not a new active ingredient. Pesticide products containing cholecalciferol have been registered in the U.S. since 1984. If the active ingredient used in the pending products were from a source registered in the U.S., the only product-specific efficacy data *required* to be submitted and reviewed for a new placepack product labeled for Norway rats, roof rats and house mice are laboratory studies conducted in accordance with:

EPA Protocol 1.217 (Rat placepack penetration)
EPA Protocol 1.209 (Rat acute dry bait)
EPA Protocol 1.218 (mouse placepack penetration)
EPA Protocol 1.210 (mouse acute dry bait)

Note that these studies must be conducted with the specific formulation(s) proposed for registration. A cursory inspection of the list of MRIDs submitted by BASF reveals that tests were indeed submitted per EPA Protocols 1.209 and 1.210, but without (apparently) the corresponding penetration studies (EPA Protocols 1.217 and 1.218). However, circumstances peculiar to the pending applications require that additional efficacy data, including data from field efficacy trials, be submitted or cited to support these proposed registrations.

Most of the submitted studies appear to be field tests, possibly including ones which were required for registration outside of the U.S. Others appear to be tests conducted using products and/or formulations which are not identical to the currently proposed formulation, or using formulations which are no longer registered (in the U.S. in the case of some of the oldest studies listed on the data matrices included in the application packages). As EPA's laboratory data are meant to stand for relevant field data for baits containing active ingredients which are already registered with EPA, BASF clearly may use field data (versus laboratory data) for this submission to support registration. However, field efficacy studies not documented as having been performed using the specific formulation(s) proposed for these products would only serve to support the utility of the active ingredient as an agent for controlling the rodent pests targeted in the trials rather than as specifically supporting 7969-GIE, 7969-GIG, or 7969-GIU.

DATA SUMMARY

House mouse – feeding pen trials

[1] The RMD allows bait blocks and "paste" formulation to be used in ready-to-use bait stations targeted for "consumer" markets but does not permit placepacks, which typically contain pelleted bait formulations, to be used in the stations. As 7969-GIG and 7969-GIU are paste formulations within placepacks, they would seem to fall into a category that the RMD was not intended to exclude from "consumer" markets.

Hughes, C. (2014a). Choice Feeding Pen Trial Study on Selontra-P Rodenticide Bait (BAS 410 HH I*), Using the Surplus Baiting Method, Against a Colony of Wild Derived Mus domesticus (Experiment 9136). Project Number: 2014/1326052, LR015/14. Unpublished study prepared by BASF plc. 10p.

MRID# 49667508

This report presents a summary of a feeding pen trial "undertaken against a colony of wild derived *Mus domesticus* [house mice]" and using methodology which reportedly complied with "BPD, 98/8/EC, Technical Notes for Guidance on Product Evaluation, Appendices to Chapter 7, Product Type 14 Efficacy Evaluation of Rodenticidal Biocidal Products". No pictures or diagrams of the test location or the enclosure were provided in the report, nor were any raw data entries provided. Mice were reportedly housed in a "semi-natural environment", further described as "an intermediate study between laboratory cage tests and field trials".

The test group consisted of 45 house mice, with 22 males and 23 females. A 1-month acclimatization period with access to a single, central container with laboratory diet was reportedly used. The acclimatization period was followed by a choice feeding test period between the same laboratory diet location/container and the addition of 4 containers of the test bait. A 10-day observation period was then to follow if any mice survived the baiting period. Using weigh-backs both before and after the presentation of the test bait and through searches for "dead and moribund" mice during the choice feeding period, Hughes reports 100% mortality and a palatability ratio of 4.3 (81.3% bait acceptance) on the first day of the choice feeding period. Given the protracted exposure to only laboratory diet preceding the first day of having the test bait as an alternative, this bait acceptance figure is unsurprising.

Though these results would appear to say something positive about a cholecalciferol bait having effectively controlled a group of house mice, there are problems with the study which severely limit its utility to EPA. These problems are listed below.

- A lack of raw data entries (e.g., drawings of the test site, feed consumption forms, etc.)
- The culling of moribund mice which may have recovered (i.e., counting "sick" mice as "dead")
- The prolonged use of laboratory diet as a maintenance ration and then as a "challenge diet" to be used against the test bait to determine palatability
- An unequal number and position of control/test diets, and no information regarding the amount of control diet provided
- No assays of the laboratory diet and test material for % cholecalciferol; no detailed test bait formulation information

For tests of bait acceptance, EPA prescribes in its protocols that a candidate test bait be tested against EPA Challenge Diet in choice feeding trials. Pre-test animals are to be maintained under test conditions for 7 days using a standard laboratory diet, and both the test material and EPA Challenge Diet are to be offered on the first test day as novel food sources, in approximately equal amounts to minimize consumption bias.[2] In EPA's former laboratory in Beltsville, MD, ground laboratory diet was found to be the *least* palatable of the dozen or so diets which were tested as potential challenge diets. The bait that became "EPA Standard Challenge Diet" was selected in large part due to its intermediate palatability, and its use has been prescribed in the EPA Protocols for more than 40 years since then. That the test bait in this study was found to achieve a high initial bait acceptance figure is not surprising given that it was the only novel food offered at the start of the choice

[2] For bait exposure periods ≥ 3 days in duration, EPA requires test baits to meet a minimum bait acceptance criterion of 33% (or 25% for bait blocks contained wax) when offered in choice tests against EPA Challenge Diet. However, even though EPA does not require a minimum bait acceptance criterion for tests with bait exposure periods shorter than 3 days, low bait acceptance is likely to result in survivors (i.e., failure to meet the minimum mortality criterion of 90%).

test, and possibly represented a "welcome change" to any mice which did not particularly care for the taste and/or the single, centralized location of the laboratory diet.

According to the summary data included in the report assigned MRID No. 49667508, bait acceptance dropped sharply over the 3-day bait-exposure period that this study turned out to have. These data were used to construct the table shown below. These results are consistent with the bait's having had high initial attraction (probably for the reasons discussed above) and having become less attractive over time to the mice that continued to feed. These data do not indicate clearly whether the consumption of laboratory diet on Day 3 was from mice which had previously consumed the toxic bait and had then become bait shy, or whether it was from mice that were simply not attracted to the bait all along.

	Day 1	Day 2	Day 3	TOTAL
Toxic Bait Consumption (g)	117	50	0	167
Laboratory Diet Consumption (g)	27	43	20	90
Total Consumption (g)	144	93	20	257
Bait Acceptance	81.2%	53.8%	0%	65.0%

Hughes reports that there was one mouse mortality on Day 2 of the bait-exposure period and 44 mortalities on Day 3. However, she also states that many of these mice, including 19 pups (<5 g), were "culled" and "euthanized" rather than having been found dead. Hughes does not state how many of the 26 larger mice, 16 to "31+" g in body weight, also were "culled".[3] Thus, the reviewer is at a loss to determine how many of these mice died without human assistance.

For efficacy tests of rodenticide baits which are to be used for the sole purpose of killing rodents, EPA's policy has been to classify rodents as dead when they are dead. Though various entities have begun moving toward euthanizing moribund individuals as a humane practice for animal testing where death is the intended result, the ultimate fate of rodents exposed to rodenticides in efficacy tests must be determined. Bait shyness from rodents surviving sublethal exposure to rodenticides is a well-documented phenomenon in rodenticide efficacy trials, and might have occurred in this one. Bait-shy rodents perpetuate infestations. As registered rodenticide baits are expected to kill many *thousands* of rodents under conditions of actual use, scientific integrity must not be suspended in favor of relieving the perceived suffering of a few test subjects in efficacy trials.

Due to the aforementioned reasons, this study may not be used to fulfill the efficacy data requirement in support of these three proposed products. As this study used procedures not acceptable to EPA, there would seem to be little point to attempting to rehabilitate it with the submission of raw data and formulation information.

Hughes, C. (2014b). Choice Feeding Pen Trial Study on Selontra-P Rodenticide Bait (BAS 410 06 I), Using the Surplus Baiting Method, Against a Colony of Wild Derived *Mus domesticus*, Bromadiolone Resistant Strain. (Experiment 15027). Project Number: 2015/1259919, LR015/15. Unpublished study prepared by BASF plc. 10p.

MRID# 49925401

This report presents a summary of a feeding pen trial "undertaken against a colony of wild derived *Mus domesticus* [house mice]" and using methodology which reportedly complied with "BPD, 98/8/EC, Technical

[3] According to Hughes, "The mice that were culled exhibited typical signs of cholecalciferol toxicity prior to death. These signs included loss of bodyweight, hunched posture, anergia and hypothermia. The times to death and signs of toxicity were typical of a cholecalciferol bait."

Notes for Guidance on Product Evaluation, Appendices to Chapter 7, Product Type 14 Efficacy Evaluation of Rodenticidal Biocidal Products". No pictures of the test location or diagrams of the enclosure were provided in the report, nor were any raw data entries provided. Mice were reportedly housed in a "semi-natural environment", further described as "an intermediate study between laboratory cage tests and field trials".

The procedures used for this trial were similar to those used for the Hughes (2014a) trial discussed above. The test group consisted of 74 house mice, with 37 males and 37 females. For this trail. Hughes (2014b) reports 100% mortality and a palatability ratio of 14.4 (93.5% bait acceptance) on the first day of the choice feeding period.

Though these results would appear to say something positive about a cholecalciferol bait having effectively controlled a group of house mice, this study has limitations similar to those discussed for the Hughes (2014a) study. These problems are listed below.

- A lack of raw data entries (e.g., drawings of the test site)
- The culling of moribund mice which may have recovered (i.e., counting "sick" mice as "dead")
- The prolonged use of laboratory diet as a maintenance ration and then as a "challenge diet" to be used against the test bait to determine palatability
- An unequal number and position of control/test diets, and no information regarding the amount of control diet provided
- No assays of the laboratory diet and test material for % cholecalciferol; no detailed test bait formulation information

That the test bait in this study was found to achieve a high initial bait acceptance figure is not surprising given that it was the only novel food offered at the start of the choice test.

According to the summary data included in the report assigned MRID No. 49925401, bait acceptance dropped sharply over the 3-day bait-exposure period that this study turned out to have. These data were used to construct the table shown below. These results are consistent with the bait's having had high initial attraction and having become less attractive over time to the mice that continued to feed. These data do not indicate clearly whether the consumption of laboratory diet on Day 3 was from mice which had previously consumed the toxic bait and had then become bait shy, or whether it was from mice that were simply not attracted to the bait all along. The 307 g of total consumption on Day 1 was only 3 g less than the total take of challenge diet on the last day of the pre-test period. Therefore, it seems clear that food intake by mice was not suppressed to any significant degree on the first day of exposure to the toxic bait. Consequently, proposed claims like "stop-feeding effect" are not supported by these results.

	Day 1	**Day 2**	**Day 3**	**TOTAL**
Toxic Bait Consumption (g)	287	135	0	422
Laboratory Diet Consumption (g)	20	61	36	117
Total Consumption (g)	307	196	36	539
Bait Acceptance	93.5%	68.9%	0%	78.3%

Hughes reports that there were 3 mouse mortalities on Day 1 of the bait-exposure period, 27 more on Day 2, and 44 more on Day 3. Although there apparently were no pups (<5 g) involved in this trial, Hughes states that some mice were "culled" and "euthanized" rather than having been found dead. Hughes does not report how many of the 74 died with and without human assistance. Consequently, the "Mean Days to Death" figure of "2.6" that she provides likely is somewhat optimistic. The problems with euthanizing test subjects in rodenticide efficacy trials are discussed in greater detail (above) for the Hughes (2014a) trial.

Due to the aforementioned reasons, this study may not be used to fulfill the efficacy data requirement in support of these three proposed products. As this study used procedures not acceptable to EPA, there would seem to be little point to attempting to rehabilitate it with the submission of raw data and formulation information.

Norway rat – feeding pen trial

Hughes, C. (2014c). Choice Feeding Tests on Selontra-P Rodenticide Bait (BAS 410 HH I*), Against Male and Female Rattus norvegicus, Wistar Strain. Project Number: LR016/14, 2014/1326053. Unpublished study prepared by BASF plc. 11p.

MRID# 49667509

This report presents a summary of a "choice feeding test" against Wistar strain rats and using methodology which reportedly complied with "BPD Technical Notes for Guidance on Product Evaluation, Product Type 14". No raw data entries were provided with the report. Rats were reportedly single-housed in a "polypropylene cage[s] 38.0 x 25.0 x 20.0 cm (l x w x h) with [a] stainless steel wire mesh lid and base, over a tray containing a paper liner".

The test group consisted of 20 rats, with 10 males and 10 females. A 3-day "acclimatization" period with access to two, identical feeding dishes containing ground laboratory diet *ad libitum* was reportedly used. One day (24 hours) prior to the choice feeding test, these dishes were replaced with two identical feeding dishes, each containing 50 grams of ground laboratory diet whicb was used to calculate pre-test bait consumption. Following this, rats were provided a 4-day choice test between ground laboratory diet and the test bait "each in excess of the rat's daily food requirement" and "offered in identical feeding dishes, symmetrically placed". Using weigh-backs both before and during the choice test and through observation of rats for "any toxic signs and mortality" for 10 days of post-exposure monitoring, Hughes reports 100% mortality by day 3 of the post-exposure monitoring period. A palatability ratio of 1.90 was reported (65.6% bait acceptance) for male subjects.[4] For females, the palatability ratio was 5.84 (85.4% bait acceptance). Due to variations among individuals, however, the palatability ratios reportedly were not statistically different between the sexes. Given the protracted exposure to only laboratory diet preceding the first day of having an alternative, this bait acceptance figure is unsurprising.

Though this would appear to say something positive about a cholecalciferol bait having effectively controlled a group of rats, this study has limitations similar to those discussed for the Hughes (2014a) study. These problems are listed below.

- A lack of raw data entries (e.g., drawings of test site)
- The culling of moribund rats which may have recovered (i.e., counting "sick" rats as "dead")
- The prolonged use of laboratory diet as a maintenance ration and then as a "challenge diet" to be used against the test bait to determine palatability

[4]This figure for palatability ratio appears to be in error, based upon information on Table 1 to the report assigned MRID No. 49667509. The daily consumption results for individual rats sum to the numbers shown in the next table below, rather than to 163.1 g for total test material take by males and 85.7 g for their total take of laboratory diet during the bait-exposure period. Dividing 163.1 g by 85.7 g seems to be responsible for Hughes' figure of 1.90 for palatability ratio. Based on the numbers summed from reported daily consumptions by individuals, the palatability ratio would be 2.80 (178.4 divided by 63.8).

- An unequal number and position of control/test diets, and no information regarding the amount of control diet provided
- No assays of the laboratory diet and test material for % cholecalciferol; no detailed test bait formulation information

That the test bait in this study was found to achieve a high initial bait acceptance figure is not surprising given that it was the only novel food offered at the start of the choice test.

According to the summary data included in the report assigned MRID No. 49667509, bait acceptance dropped sharply over the 3-day bait-exposure period that this study turned out to have. These data were used to construct the table shown below. These results are consistent with the bait's having had high initial attraction and having become less attractive over time to the rats that continued to feed. These data do not indicate clearly whether the consumption of laboratory diet on Day 3 was from rats which had previously consumed the toxic bait and had then become bait shy, or whether it was from rats that were simply not attracted to the bait all along. Consumption on Day 3 was so low on that it is likely that the 19 rats that survived until that day were too sick to do much of anything. Total consumption on Day 1 was higher than the total take of challenge diet on the last day of the pre-test period. Therefore, it seems clear that food intake by rats was not suppressed on the first day of exposure to the toxic bait. Consequently, proposed claims like "stop-feeding effect" are not supported by these results.

	Day 1	Day 2	Day 3	TOTAL
Toxic Bait Consumption (g) – Males	174.7	3.2	0.5	178.4
Laboratory Diet Consumption (g) – Males	44.0	17.8	2.0	63.8
Total Consumption (g) – Males	218.7	21.0	2.5	242.2
Bait Acceptance –Males	79.7%	15.2%	20.0%	73.7%
Toxic Bait Consumption (g) – Females	159.7	20.7	0	180.4
Laboratory Diet Consumption (g) - Females	8.3	20.7	1.9	30.9
Total Consumption (g) – Females	168.0	41.4	1.9	211.3
Bait Acceptance – Females	95.1%	50.0%	0%	85.4%
Toxic Bait Consumption (g) – Total	334.4	23.9	0.5	358.8
Laboratory Diet Consumption (g) - Total	52.3	38.5	3.9	94.7
Total Consumption (g) – Total	386.7	62.4	4.4	453.5
Bait Acceptance – Total	86.5%	38.3%	11.4%	79.1%

Hughes reports that there were no rat mortalities on Day 1 of the bait-exposure period and 4 mortalities (all males) on Day 2, with the remaining 15 rats having died or been "culled" on Day 3. Hughes does not indicate how many of the 20 rats used in this trial (which apparently lacked a control group) died without human assistance. She reports that observed premorbid signs of toxicosis included "hunched posture, piloerection, oligaemia, loss of bodyweight and reduced eating." It is not clear which of these qualified as the "severe signs of cholecalciferol toxicity" that would have led to the culling of live rats. The problems with euthanizing test subjects in rodenticide efficacy trials are discussed in greater detail (above) for the Hughes (2014a) trial.

Due to the aforementioned reasons, this study may not be used to fulfill the efficacy data requirement in support of these three proposed products. As this study used procedures not acceptable to EPA, there would seem to be little point to attempting to rehabilitate it with the submission of raw data and formulation information.

House mouse – laboratory trials

Doig, A. (2015) BAS 410 06 I: Acute Toxicity Bait Study in Mice. Project Number: 18634/15, 2015/7001614. Unpublished study prepared by Stillmeadow, Inc. 35p.

MRID# 49667518

This report describes a laboratory feeding trial purportedly conducted in accordance with EPA Protocol 1.210, a method for testing acute dry baits for efficacy against house mice (and for establishing "single-feeding" claims for second-generation anticoagulants if a single bait exposure day is used). As this product is contained within a wrapper (placepack), it is unclear whether this test is meant to stand for EPA's required placepack penetration test for house mice (Protocol 1.218). For reasons which will be discussed below, EPA Protocol 1.210 is not an ideal method for testing an intact placepack bait.

Animal Care and Maintenance

For the testing, 40 house mice (albino Swiss-Webster strain) were reportedly used, with a 50:50 sex ratio. 10 mice of each sex comprised the test group, and 10 mice of each sex comprised the control group. At the start of the study (day -1) the male weight range was 31.1 to 35.5 grams, and the females were 27.8 to 32.6 grams. The average weight different between the sexes was reportedly 3.9 grams for test mice, and 4.1 grams for control mice These figures are very close to meeting the criteria prescribed in Protocol 1.216, which specifies a weight range of 15-35 grams and a maximum average difference in weights between the sexes of 5 grams.

According to the study report, mice were group-housed in "65.4 x 46.7 x 33.7 cm solid bottom, 19 gallon Sterilite container[s]", which provides a bottom surface area of about 3054 cm^2 (3.28 ft^2). While this enclosure size exceeds the minimum 2000 cm^2 (2.15 ft^2) criterion prescribed in Protocol 1.216 for group-housed mice, it is unclear whether it meets the criterion of being a "solid-bottom, all-metal cage designed to hold laboratory mice *or* [a] *specially constructed or modified cage suitable for maintaining house mice for this type of study*".[5] As group-housed mice may interact in various ways, including aggressively at times, Protocol 1.210 prescribes that at least 3 shelters are to be used in the enclosures.[6]

No information regarding the temperature and relative humidity readings that occurred in the test room was provided aside from the entries "Actual Temp – 20-24°C" and "Rel. Humidity – 25-93%" on page 9 of the report. Raw data entries for temperature and relative humidity bracketing the test period should be supplied to provide information about how these figures were reached. Taken a face value, the relative humidity in the test room strayed in both directions from that prescribed by Protocol 1.210 (50-55%). Without citing relevant data, the author explains this (and other) deviations from protocol on page 13 of the report by stating that "the listed deviations did not adversely affect the study". This conclusion is speculative, at best.

A 12-hour light/dark cycle was reportedly maintained with artificial lighting presumably not exceeding 200-ft candles. Access to the laboratory was restricted to personnel conducting the test.

Procedures

All mice used in the study were reportedly acclimated to test conditions for 7 days prior to the actual testing. Page 9 of the report indicates that a commercial rodent diet was provided, along with water *ad-libitum* from

[5] A plastic container of this size holding 5 individual mice likely did not ventilate very well, and thus may have resulted in a less sanitary environment than a steel cage would have provided.

[6] In extreme cases, test mice may defend access to a more preferred food item against conspecifics, which may skew bait acceptance and/or mortality figures one way or the other.

"water bowls". Water provided in bowls or other "open cup" type waterers (including those which are automatic or gravity-fed) are specifically recommended against by EPA's Protocols due to their higher potential to become fouled, spilled, or nested-in by mice. This could have posed an even larger problem in this instance, as the researcher attempting to weigh back diets to calculate consumption would have had the added challenge of dealing with food/water clinging to the placepack wrapping and/or bits of placepack being scattered about (and/or eaten) in a Sterilite (plastic) enclosure without a removable tray.[7]

The test group consisted of 10 males and 10 females, grouped 5-per-enclosure, for a total of 4 enclosures. The amount of each food provided to mice during the pre-test holding and test period was not stated explicitly in the narrative portion of the report. However, the specific amounts provided during the test period can be determined from the "food and bait consumption" data provided on pages 19-23 and the amounts provided during the pre-test holding period can be at least assumed based upon the "PROTOCOL FOR STUDY" document appended to the back of the report.[8] Based upon this document, it appears that a laboratory diet (PMI Feeds, Inc. Formulab #5008) was provided *ad libitum* during the pre-test holding period.

For the first day of testing, about 60 grams of the test material was provided per enclosure alongside about 50 grams of the EPA Challenge Diet for test mice, a procedure which may have biased the choice-feeding results during this 2-day exposure period.[9] Based upon the application materials submitted to EPA in support of registration, 60 grams of bait would be supplied through the use of 3 placepacks. For the control group, 10 males and ten 10 females were reportedly maintained concurrently with the test group (in a similar configuration). The control group was given about 50 grams of the EPA Challenge Diet in a single container for the duration of the test period (12 days in this case). Though this procedure would have provided a minimum of 10 grams per mouse per day, Protocol 1.210 stipulates that the control mice are to be offered "amounts and numbers of containers equivalent to those used for the test group". In other words, each control mouse enclosure should have been provided 2 separate containers of EPA Challenge Diet instead of just one. Collection and replenishment of the challenge diet for control mice was presumably done exactly as was done for the test mice. To minimize the effects of feeding preference for test mice, the two substances were reportedly reversed between days 1 and 2.[10] Information about how the bait was presented (i.e., whether it was provided within its placepack wrapping) was lacking in the report. However, the report refers to the test material simply provided as "bait", so it must be assumed that whole packs were provided to the mice. To measure the amount of each feeding substance eaten by the mice, each day the

> Food was recovered and weighed to establish exact food consumption data. The gross weight of bait and/or challenge diet feed give, remaining from the previous study day, and consumed between feedings was determined daily and all consumed feed returned to approximate starting weight by the addition of bait or challenge diet.

No mention is made regarding the handling of chewed (or whole) placepack material. The test substance was reportedly removed after 2 days of choice feeding, with EPA Challenge Diet being continued for the remaining 10 days, or until death. For control mice, EPA Challenge Diet was provided for the entire 12-day period.

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[7] EPA Protocol 1.217 was specifically designed as a means of addressing problems related to the collection of spilled material, separating diet from non-food items (e.g. feces, pieces of the actual placepack), and obtaining accurate consumption data. Basically, it eliminates the problem of measuring consumption data and instead requires the number of "chewed-into packs" to be reported along with lethality consumption data are to be collected in a separate protocol using the unwrapped product (EPA Protocol 1.210).

[8] It would be far preferable for Stillmeadow to clearly state up front what procedures were actually done during testing rather than leaving the reader to assume that the appended "PROTOCOL FOR STUDY" procedures were actually performed.

[9] During the bait exposure period of feeding trials, equal amounts of test material and EPA Challenge Diet are to be offered to minimize potential feeding bias of the test subjects.

[10] Assuming that test subjects had not already removed any of the placepacks from the food container and moved them to some other location within the enclosure.

Testing was presumably completed on 03/07/15. After death, each mouse was to be collected and weighed immediately upon discovery. Any surviving test mice and all control mice were to be weighed at the end of the test period.

Results

Within the 12 days of testing, 18 of the 20 test-group mice died (90% mortality) and none of the control-group mice died (0% mortality).[11] This meets the Protocol 1.210 criteria of 90% mortality for the test group, and not greater than 10% mortality for control group.

Days to death for test mice are provided in the following table.

	Day												
	0	1	2	3	4	5	6	7	8	9	10	11	12
No. Dead	0	0	0	3	5	6	9	12	16	18	18	18	18

All 20 of the test mice, and 13 of 20 control mice lost weight during the testing period. The test mice lost an average of 7.4 grams of weight versus the average of 0.5 grams lost by the control mice. Test mice observations recorded on p. 24 of the report indicated only "decreased activity-extreme" as pre-morbid symptoms for the mortalities. For the 2 survivors, "decreased activity-extreme" was initially recorded for days 3-7 of the study, but was followed up with "decreased activity-slight" on days 8-9. This result is consistent with the survivors having consumed a toxic dose of the bait, but then having eventually recovered on subsequent days. Control mice observations only included "NOA", or no observable abnormalities.

Composite bait consumption values for test mice are provided in the following table.

	Bait Consumed (g)	Challenge Diet Consumed (g)	Percent Bait Acceptance
male	19.9	61.2	24.5%
female	24	67	26.4%
combined	43.9	128.2	25.5%

Bait acceptance for the test mice was 25.5%. Acceptance by female mice (26.4%) was reported to be nearly identical to that by males (24.5%). For females, bait acceptance declined considerably from the first to the second day of the bait-exposure period. For Day 1, acceptance hy females was 31.3% (19.4 g bait vs. 42.6 g OPP diet). For Day 2, acceptance by females dropped to 15.9% (4.6 g bait vs. 24.4 g OPP diet). For males, acceptance on Day 1 was 24.9% (14.9 g bait vs. 45.0 g OPP diet) and 23.6% (5.0 g bait vs. 16.2 g OPP diet).

Certificate of Analysis – EPA Challenge Diet and Test Bait

Analyses of the "BAS 410 I" batch #SXE05714/06 for percent cholecalciferol were provided on pages 7 and 35 of the report. Results indicate 0.0702% and 0.0704% cholecalciferol. A separate analysis was performed for the EPA Challenge Diet, with results "below the limit of quantification" of 0.00001006 and 0.00001148% for both tested batches.

[11] For the testing of acute baits, all that is prescribed by EPA Protocol 1.210 following a 2-day bait exposure period is 5 days of post-exposure monitoring. The protocol drafted by Stillmeadow Incorporated for this specific study called for a 10-day post-exposure monitoring period, which is consistent with an option provided in Protocol 1.210 "for 'single-feeding' tests of anticoagulant rodenticide baits. As only 14 mice had died after 5 days of the post-exposure monitoring period had elapsed, the extended monitoring period afforded time for realizing the 90% mortality result reported for this trial.

Formulation of EPA Challenge Diet and Test Bait

The specific batches of EPA Challenge Diet identified in this report were "Lot #S9021115" and "Lot #S9022615", and information regarding their ingredients and creation was provided on p. 9 and 11 of the report. Based upon the expiration date of "Aug15" provided in the report and information regarding its ingredients, it appears that the criteria prescribed in Protocol 1.210 regarding EPA Challenge Diet are met.[12]

Formulation data for the test bait were not submitted with the original application package. However, these data were requested by EPA and were received and routed for review on 07/20/16. Two separate batch sheets for "batch #SXE05714/06" were provided, with one raw batch sheet dated 10/27/14 listing the bulk of the ingredients, and another computer-generated table reportedly providing additional information related to ingredients and percentages of the tested batch. A comparison of these data to the proposed CSFs dated 03/30/16 indicates that the tested batch matches the proposed Basic CSF. All of the proposed Alternate CSFs differ from the tested batch. As EPA has no data for these untested formulas, data generated for batch #SXE05714/06 will not support any of the proposed alternate formulations.

CONCLUSIONS and RECOMMENDATIONS

There are several problems associated with the methodology used for this test.

1. At least three 3 hide shelters are to be used for mice which are group-housed with 5 mice per enclosure to minimize agonistic behavior; none were reportedly used.
2. Plastic "Sterilite" enclosures were used instead of the "all metal cages" prescribed in EPA Protocol 1.210.
3. Open "cup" style waterers were used, which are specifically recommended against in the EPA Protocols due to problems associated with fouling, nesting and spillage.
4. Some procedural details were omitted and could not be determined even with the aid of the appended "PROTOCOL FOR STUDY" document (e.g., how diet/spillage was handled with regard to the actual placepack wrapping).
5. During the 2-day bait exposure period, a larger amount of test bait was provided than EPA Challenge Diet to the test subjects, potentially biasing acceptance.
6. Raw data sheets for bait consumption, body weights, environmental conditions, etc., were not included in or appended to the report.

For the reasons previously discussed, Protocol 1.210 is not an appropriate method to determine bait acceptance for placepack baits. However, this trial does seem to indicate mouse willingness to chew into the provided placepacks. Additionally, the prescribed mortality criterion of $\geq 90\%$ was also met, albeit after a somewhat extended post-exposure monitoring period.[13] **Despite the problems noted in this review, this study could be accepted to establish the placepack penetration portion of the efficacy requirement regarding house mice (i.e., what would he met by conducting a test in accordance with EPA Protocol 1.218 of the house mouse efficacy data requirement.)**

Note that the consumption of sub-lethal amounts of bait and the apparent recovery of some individuals that occurred in this trial underscores the mistake of euthanizing moribund animals in rodenticide efficacy tests.

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[12] As EPA Challenge Diet is semi-perishable, it is required that it either be used immediately upon preparation or stored in such a way that its palatability is not compromised prior to its later use.

[13] The somewhat protracted times-to-death for mice in this trial may affect labeling claims regarding "speed of kill".

Doig, A. (2016) BAS 410 06 I: Acute Toxicity Unwrapped Bait Study in Mice. Project Number: 19164/15, 2015/7006447. Unpublished study prepared by Stillmeadow, Inc. 36p.

MRID# 49667520

This report describes a laboratory feeding trial purportedly conducted in accordance with EPA Protocol 1.210, a method for testing acute dry baits for efficacy against house mice (and for establishing "single-feeding" claims for second-generation anticoagulants if a single bait exposure day is used). Aside from the bait having been provided "unwrapped", this study appears to have been conducted similarly to the mouse study reviewed above for MRID# 49667518.

Animal Care and Maintenance

For the testing, 40 house mice (ND4 strain) were reportedly used, with a 50:50 sex ratio. The ND4 is an atypical strain for EPA testing purposes. Ten 10 mice of each sex comprised the test group, and 10 mice of each sex comprised the control group. At the start of the study (day -1) the male weight range was 25.6 to 30.2 grams, and the females were 20.3 to 26.2 grams. The average weight difference between the sexes was 4.8 grams. These figures meet the criteria prescribed in Protocol 1.210, which specifies a weight range of 15-35 grams and a maximum average difference in weights between the sexes of 5 grams.

According to the study report, mice were group-housed in "59 x 40 x 33 cm solid bottom, plastic container[s]", which provides a bottom surface area of about 2360 cm^2 (2.54 ft^2). While this enclosure size exceeds the minimum 2000 cm^2 (2.15 ft^2) criterion prescribed in Protocol 1.210 for group-housed mice, it is unclear whether it meets the criterion of being a "solid-bottom, all-metal cage designed to hold laboratory mice *or* [a] *specially constructed or modified cage suitable for maintaining house mice for this type of study*".[14] As group-housed mice may interact in various ways, including aggressively at times, Protocol 1.210 prescribes that at least 3 shelters are to be used in each enclosure.[15] Based upon the appended PROTOCOL FOR STUDY, it appears that 3 shelters may have been used per enclosure.

No information regarding the temperature and relative humidity readings that occurred in the test room was provided aside from the entries "Actual Temp – 19-23°C" and "Rel. Humidity – 46-70%" on page 8 of the report. Raw data entries for temperature and relative humidity bracketing the test period should be supplied to provide information about how these figures were reached. Taken at face value, the temperature and relative humidity in the test room did not meet the criteria prescribed by Protocol 1.210 of 20-25°C and 50-55%, respectively. Without citing relevant data, the author explains these deviations from protocol on page 12 of the report by stating that "The deviation did not adversely affect the study". This conclusion is speculative, at best.

A 12-hour light/dark cycle was reportedly maintained with artificial lighting presumably not exceeding 200-ft candles. Access to the laboratory was restricted to personnel conducting the test.

Procedures

All mice used in the study were reportedly acclimated to test conditions for 7 days prior to the actual testing. Page 8 of the report indicates that a commercial rodent diet was provided, along with water *ad-libitum* from "water bowls". Water provided in bowls or other "open cup" type waterers (including those which are

[14] A plastic container of this size holding 5 individual mice likely did not ventilate very well, and thus may have resulted in a less sanitary environment than a steel cage would have provided.

[15] In extreme cases, test mice may defend access to a more preferred food item against conspecifics, which may skew bait acceptance and/or mortality figures one way or the other.

automatic or gravity-fed) are specifically recommended against by EPA's Protocols due to their higher potential to become fouled, spilled, or nested-in by rodents.

The test group consisted of 10 males and 10 females, grouped 5-per-enclosure, for a total of 4 enclosures. The amount of each food provided to mice during the pre-test holding and test period was not stated explicitly in the narrative portion of the report. However, the specific amounts provided during the test period can be determined in the "food and bait consumption" data provided on pages 18-24 and the amounts provided during the pre-test holding period can be at least assumed based upon the "PROTOCOL FOR STUDY" document appended to the back of the report.[16] Based upon this document, it appears that a commercial rodent diet (PMI Feeds, Inc. Formulab #5008) was provided *ad libitum* during the pre-test holding period.

For the first day of testing, about 60 grams of the test material was provided per enclosure alongside about 50 grams of the EPA Challenge Diet for test mice, a procedure which may have biased the choice-feeding results during this 2-day exposure period.[17] Based upon the application materials submitted to EPA in support of registration, 60 grams of bait would be supplied through the use of 3 placepacks. For the control group, 10 males and ten 10 females were reportedly maintained concurrently with the test group (in a similar configuration). The control group was given about 50 grams of the EPA Challenge Diet in a single container for the duration of the test period (12 days in this case). Though this procedure would have provided a minimum of 10 grams per mouse per day, Protocol 1.210 stipulates that the control mice are to be offered "amounts and numbers of containers equivalent to those used for the test group". In other words, each control mouse enclosure should have been provided 2 separate containers of EPA Challenge Diet instead of just one. Collection and replenishment of the challenge diet for control mice was presumably done exactly as was done for the test mice. To minimize the effects of feeding preference for test mice, the two substances were reportedly reversed between days 1 and 2. To measure the amount of each feeding substance eaten by the mice, each day the

> Amount of food and/or bait consumed was determined daily and were [sic] returned to the approximate starting weight by the addition of bait or challenge diet. Weighing accuracy was to the nearest 0.5 gram. If food became fouled by urine or feces, the food was replaced in each container. Spilled food was recovered and weighed to establish exact food consumption data. If food spillage was damp, it was dried to approximately its original moisture content before weighing.

The test substance was reportedly removed after 2 days of choice feeding, with EPA Challenge Diet being continued for the remaining 10 days, or until death. For control mice, EPA Challenge Diet was provided for the entire 12-day period.

Testing was presumably completed on 08/01/15 (day 12). After death, each mouse was to be collected and weighed immediately upon discovery. Any surviving test mice and all control mice were to be weighed at the end of the test period.

Results

[16] It would be far preferable for Stillmeadow to clearly state up front what procedures were actually done during testing rather than leaving the reader to assume that the appended "PROTOCOL FOR STUDY" procedures were actually performed.
[17] During the bait exposure period of feeding trials, equal amounts of test material and EPA Challenge Diet are to be offered to minimize potential feeding bias of the test subjects.

Within the 12 days of testing, 12 of the 20 test-group mice died (60% mortality) and none of the control-group mice died (0% mortality).[18] This falls well short of the Protocol 1.210 criterion of at least 90% mortality for the test mice.

Days to death for test mice are provided in the following table.

	Day												
	0	1	2	3	4	5	6	7	8	9	10	11	12
No. Dead	0	0	0	3	6	6	7	8	10	11	11	11	12

Eighteen 18 of the 20 test-group mice, and 12 of 20 control-group mice lost weight during the testing period. Test mice observations recorded on p. 25-26 of the report are presented in the following table.

	Observation						
Animal	Activity decrease - slight	Activity decrease - moderate	Piloerection	Hunched posture	Ptosis	Alopecia around eyes	Mortality
26-M	x						-
27-M	x						-
29-M	x						-
30-M	x						-
31-M	x						-
34-M	x	x	x	x	x		-
36-M	x	x	x	x	x		Dead
37-M		x	x				Dead
38-M	x	x					-
39-M	x	x	x	x	x	x	Dead
3-F	x	x	x	x			Dead
5-F	x	x	x	x	x		Dead
6-F	x		x				Dead
8-F		x	x				Dead
9-F	x	x	x				Dead
12-F		x	x				Dead
13-F		x					Dead
16-F							-
17-F		x	x	x	x		Dead
20-F		x	x				Dead

For the 8 survivors (7 males and 1 female), the males reportedly exhibited at least some symptoms of toxicity, whereas the female did not. This result is consistent with the male survivors having consumed a toxic dose of the bait, but then having eventually recovered on subsequent days. Control mice observations only included "NOA", or no observable abnormalities.

Composite bait consumption values for test mice are provided in the following table.

	Bait Consumed (g)	Challenge Diet Consumed (g)	Percent Bait Acceptance
male	4.3	68.7	5.9%
female	13.6	47.4	22.3%
combined	17.9	116.1	13.4%

[18] For the testing of acute baits, all that is prescribed by EPA Protocol 1.210 following a 2-day bait exposure period is 5 days of post-exposure monitoring. However, as only 8 mice had died after 5 days in this testing, it is likely that BASF wished to extend this post-exposure monitoring to permit additional time for mice to die.

Bait acceptance for the test mice was 13.4%. Acceptance by female mice (22.3%) was reported to be higher than that by males (5.9%). For 5 of the 7 male survivors which were housed together in cage number "5-M", data entries for bait consumption indicate that very little of the test bait was consumed compared to the Challenge Diet for and are consistent with those individuals not having eaten enough of the test bait to get a lethal dose. The situation is less clear for the other surviving male and the lone surviving female, though the most likely explanation for rodents surviving rodenticide efficacy trials is a lack of toxic bait consumption.

One problem that seems to have occurred in this trial is the reporting of negative consumption values on the 2nd day of bait exposure.[19] As mice cannot vomit, this is an impossible result.

Certificate of Analysis – EPA Challenge Diet and Test Bait

Analyses of the "BAS 410 06 I" batch #SXE05714/06 for percent cholecalciferol was provided on page 7 of the report. The analyses for this particular study were performed by a German laboratory (Institut Kuhlmann) using the FPV-64 analytical method. Results from this laboratory indicated 0.0809% cholecalciferol. A separate analysis for percent cholecalciferol in the EPA Challenge Diet (batch #S9071715) was apparently not performed or provided based upon the "Not provided to testing facility" note on page 7.[20]

Formulation of EPA Challenge Diet and Test Bait

The specific batch of EPA Challenge Diet identified in this report was "Lot #S9071715" and information regarding its ingredients and its creation was provided on p. 8 of the report. Aside from a lack of an analysis of the Challenge Diet for percent cholecalciferol, information provided in the report indicate that its creation and handling were otherwise appropriate.

CONCLUSIONS and RECOMMENDATIONS

This study is rejected for failure to achieve the minimum mortality criterion of ≥ 90%. Additional problems include weigh-back figures which were inaccurate to some degree, and not providing an analysis of EPA Challenge Diet for percent cholecalciferol. Due to these problems, there would seem to be little point in attempting to rehabilitate this study by supplying raw data and formulation information.

Note that the consumption of sub-lethal amounts of bait and the apparent recovery of some individuals that occurred in this trial underscores the mistake of euthanizing moribund animals in rodenticide efficacy tests.

Richter, D. (2016) BAS 410 06 I Soft Block Unwrapped: Mouse Acute Dry Bait Laboratory Test Method (OPP 1.210). Project Number: ASF/15/008, 2015/7006445. Unpublished study prepared by BASF Corporation. 43p.

MRID# 49667525

This report describes a laboratory feeding trial purportedly conducted in accordance with EPA Protocol 1.210, a method for testing acute dry baits for efficacy against house mice (and for establishing "single-feeding" claims

[19] In this report, negative consumption values were marked "a" with the corresponding footnote "Bait blocks chewed despite weight increase of blocks. Unable to calculate amount consumed". As it is not possible to have more bait present than what was provided the previous day, the most likely error is related to some aspect of the weigh back procedure for handling spilled and/or damp/fouled material.

[20] It is unclear why this analysis was not performed, as it is a requirement specified by EPA's Protocols and is also noted as a requirement on page 8 of Stillmeadow's own PROTOCOL FOR STUDY document. No explanation is provided under "Protocol Deviations" on page 12 of the report.

for second-generation anticoagulants if a single bait exposure day is used). This appears to be a "repeat" of the study submitted as MRID# 49667520.

Animal Care and Maintenance

For the testing, 40 "Horst" strain house mice were reportedly used, with a 50:50 sex ratio. The "Horst" strain of house mice is an atypical strain for EPA testing purposes. According to the appended Protocol for Study, the mice were "derived from an in-house wild colony breeding at *Labor Prof. Matuschka*". Ten 10 mice of each sex comprised the test group, and 10 mice of each sex comprised the control group. At the start of the study (day -1) the male weight range was 17.1 to 25.1 grams, and the females were 15.2 to 21.4 grams. The average weight difference between the sexes was 3.6 grams. These figures meet the criteria prescribed in Protocol 1.210, which specifies a weight range of 15-35 grams and a maximum average difference in weights between the sexes of 5 grams.

According to the study report, mice were group-housed in 69 x 60 x 58 cm white polypropylene enclosures, which would have provided a bottom surface area of about 4140 cm^2 (4.46 ft^2). While this enclosure size essentially doubles the minimum 2000 cm^2 (2.15 ft^2) criterion prescribed in Protocol 1.210 for group-housed mice, it is unclear whether it meets the criterion of being a "solid-bottom, all-metal cage designed to hold laboratory mice *or* [a] *specially constructed or modified cage suitable for maintaining house mice for this type of study*".[21] Food containers were apparently fastened on a centrally-located "bridge made from stainless steel mesh". This arrangement did not meet the criteria of Protocol 1.210 which specifies food containers to be placed "on opposite sides of the front of the cage". As group-housed mice may interact in various ways, including aggressively at times, Protocol 1.210 prescribes that at least 3 shelters are to be used in each enclosure. Page 8 indicates that 3 shelters were indeed used per enclosure.

The entries "Actual Temp – 19-23°C" and "Rel. Humidity – 46-70%" were provided on page 8 of the report. Raw data entries for temperature and relative humidity were provided but are difficult to read. Taken at face value, the relative humidity in the test room did not meet the criteria prescribed by Protocol 1.210 of 50-55%. Without citing relevant data, the author explains these deviations from protocol on page 12 of the report by stating that "The listed deviations did not adversely affect the study". This conclusion is speculative.

A 12-hour light/dark cycle was reportedly maintained, with access to the laboratory having been restricted to personnel conducting the test.

Procedures

All mice used in the study were reportedly acclimated to test conditions for 7 days prior to the actual testing. Page 9 of the report indicates that a commercial rodent diet was provided ("Hoveler Mause-und Rattenfutter"), along with water *ad-libitum* from "water bottles".

The test group consisted of 10 males and 10 females, grouped 5-per-enclosure, for a total of 4 enclosures. For the 2-day bait exposure period, 50.0 g of standard EPA Challenge Diet along with about 60 grams of bait (3 soft blocks) were reportedly provided to each mouse enclosure, per day. This procedure may have biased the choice-feeding results during this 2-day exposure period to some degree.[22] For the control group. 10 males and ten 10 females were reportedly maintained concurrently with the test group, and in a similar 5-per-enclosure

[21] A plastic container housing 5 individual mice likely did not ventilate very well, and thus may have resulted in a less sanitary environment than a similarly-sized steel cage would have provided.

[22] During the bait exposure period of feeding trials, equal amounts of test material and EPA Challenge Diet are to be offered to minimize potential feeding bias of the test subjects.

arrangement. The control group was given about 50 grams of the EPA Challenge Diet per day in a single container for the entire 18-day test period (2 days of bait exposure; 16 days post-exposure monitoring).[23] To minimize the effects of feeding preference for test-group mice, the two substances were reportedly reversed between days 1 and 2 (the bait exposure period). Information about how the bait was presented was provided on page 11 of the report. To measure the amount of each feeding substance eaten by the mice, each day the

> Food was recovered and weighed to establish exact food consumption data. Any spilled bait or challenge diet was retrieved from beneath the bridge and added to the appropriate container. Any fecal material was removed from the containers and the metal dish. Contents of the containers that appeared spoiled by urine was left to dry overnight. The gross weight of bait and/or challenge diet feed given, remaining from the previous study day, and consumed between feedings was weighed to the nearest 0.1 g daily and all consumed feed returned to approximate starting weight by the addition of bait or challenge diet.

The test substance was reportedly removed after 2 days of choice feeding, with EPA Challenge Diet being continued for the remaining 16 days, or until death. For control-group mice, EPA Challenge Diet was provided for the entire 18-day period.

Testing was presumably completed on 10/14/15 (day 18). After death, each mouse was to be collected and weighed immediately upon death. Any surviving test-group mice and all control-group mice were to be weighed at the end of the test period.

Results

Within the 18 days of testing, 13 of the 20 test-group mice died (65% mortality) and none of the control-group mice died (0% mortality). This falls well short of the Protocol 1.210 criterion of at least 90% mortality for the test mice.

Days to death for test-group mice are provided in the following table.

	Day																		
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
No. Dead	0	0	0	0	0	0	5	8	8	9	9	9	10	10	11	12	12	12	13

All 20 test-group mice, and all 20 control-group mice lost weight during the testing period.[24] Test-group pre-morbid observations recorded on page 26 of the report indicated "piloerection" and "hunched posture" for the 13 dead mice. For the 7 survivors, recordings of "hunched posture" were entered for all 7, and "piloerection" was entered for 5 of the 7. This result is consistent with the survivors having consumed a toxic dose of the bait, but then having eventually recovered on subsequent days. Control-group health observations only included "NOA", or no observable abnormalities.

Composite bait consumption values for test mice are provided in the following table.

[23] This test differed from the one conducted by Stillmeadow (MRID# 49667520) in that the post-exposure monitoring was extended from 10 days to 16 days. This was clearly done to allow additional time for any test mice who might have died to do so.

[24] A note on page 12 indicates that for 2 of the female enclosures and 1 male enclosure, some of the dead mice in the test group had been partially consumed by conspecifics before they were removed and weighed, likely skewing the measurements. Clearly this is one of the potential negative aspects of group housing rodents in efficacy trials.

	Bait Consumed (g)	Challenge Diet Consumed (g)	Percent Bait Acceptance
male	28.4	39.1	42.1%
female	25.3	34.4	42.4%
combined	53.7	73.5	42.2%

Bait acceptance for the test mice was 42.2%. Acceptance by female mice (42.4%) was reported to be nearly identical to that by males (42.1%). The poor mortality result generated from this test is most likely attributable to several mice not having eaten enough of the test bait to get a lethal dose. However, as mice were group-housed, it is somewhat difficult to state with certainty that all of the survivors consumed less of the toxic bait in all cases than those which reached mortality. However, 4 of the 5 male survivors apparently were from cage "6 M", which had a composite bait acceptance of 48.5%. That result was higher than the composite acceptance (37.9%) for cage "5 M", which had 4 mortalities and 1 survivor. For both sexes, bait acceptance and total consumption decreased somewhat over the course of the bait-exposure period. On the first day, males reportedly consumed 35.9 g of bait plus challenge diet and accepted the bait as 46.8% of total intake. On the second day, males consumed 31.6 g of both diets combined and accepted the toxic bait at 36.7%. For females, Day-1 acceptance was 44.6% with 33.4 g of total intake. On Day 2, females accepted the bait at 39.8% with 26.1 g consumption of both diets combined.

Certificate of Analysis – EPA Challenge Diet and Test Bait

Two 2 analyses of the "BAS 410 06 I" batch #0014248520 for percent cholecalciferol were provided on pages 40 and 43 of the report. The analyses for this particular study were performed by a German laboratory (Institut Kuhlmann) using the "UHPLC-(QqQ)MS" analytical method. Results from these assays indicated 0.07382 and 0.07394% cholecalciferol. Separate analyses for percent cholecalciferol in the EPA Challenge Diet (batches #15-01 and #15-02) were performed by the same laboratory and by use of the same method and generated results of $\leq$ 0.0001% cholecalciferol in that diet.

Formulation of EPA Challenge Diet and Test Bait

The specific batches of EPA Challenge Diet identified in this report were "Lot #15-01" and "Lot #15-02". Information regarding the ingredients and creation of these batches was provided on pages 9-11 of the report. Taken at face value, the creation and handling of the EPA Challenge Diet were mostly appropriate. Note that Protocol 1.210 specifies that storage of Challenge Diet is to be "at -18°C or below until it is to be used". Page 30 of the report indicates that the Challenge Diet [will be] "maintained at -18 ± 5°C until used", which must be assumed to be non-guideline in the absence of data entries noting the specific freezer temperatures which occurred.[25]

CONCLUSIONS and RECOMMENDATIONS

This study is rejected for failure to achieve a minimum of 90% mortality in house mice. It must be concluded that the results generated from both this study and the study assigned MRID# 49667520 indicate that this particular bait would not perform well against house mice.

Note that the consumption of sub-lethal amounts of bait and the apparent recovery of some individuals that occurred in this trial underscores the mistake of euthanizing moribund animals in rodenticide efficacy tests.

[25] As EPA Challenge Diet is semi-perishable, it is required that it either be used immediately upon preparation or stored in such a way that its palatability is not compromised prior to its later use. No raw data entries were supplied indicating the specific freezer temperatures used to maintain the Challenge Diet.

Norway rat – laboratory trials

Doig, A. (2015) BAS 410 06 I: Acute Toxicity Bait Study in Rats. Project Number: 18635/15, 2015/7001616. Unpublished study prepared by Stillmeadow, Inc. 35p.

MRID# 49667517

This report describes a laboratory feeding trial purportedly conducted in accordance with EPA Protocol 1.209, a method for testing acute dry baits for efficacy against Norway rats (and for establishing "single-feeding" claims for second-generation anticoagulants if a single bait exposure day is used). As this product is contained within a wrapper (placepack), it is unclear whether this test is meant to fulfill EPA's Protocol 1.209, or Protocol 1.217 (the placepack penetration test for Norway rats).

Animal Care and Maintenance

For the testing, 40 Norway rats (Wistar strain) were reportedly used, with a 50:50 sex ratio. 10 rats of each sex comprised the test group, and 10 rats of each sex comprised the control group. At the start of the study (day -1) the male weight average was 339.9 and 349.6 grams, for control and test rats, respectively. The females were 237.4 and 237.9 grams for control and test rats, respectively. The average weight difference between the sexes was reportedly 102.5 grams for control rats, and 111.7 grams for test rats. This maximum average difference between the sexes is quite a bit higher than the Protocol criterion of 65 grams (i.e., the males, on average, were larger than the females).

According to the study report, rats were single-housed in 17 x 18 x 7.5 inch "stainless steel suspended cages" with solid bottoms, which provides a bottom surface area of about 306 in^2 (2.13 ft^2). This cage size meets the minimum 0.538-2.15 ft^2 criterion prescribed in Protocol 1.209 for single-housed rats.

No information regarding the temperature and relative humidity readings that occurred in the test room was provided aside from the entries "Actual Temp – 20-24°C" and "Rel. Humidity – 22-76%" on page 8 of the report. Raw data entries for temperature and relative humidity bracketing the test period should be supplied to provide information about how these figures were reached. Taken at face value, the relative humidity in the test room strayed in both directions from that prescribed by Protocol 1.209 (50-55%). Without citing relevant data, the author explains this (and other) deviations from protocol on page 13 of the report by stating that "the deviations listed did not adversely affect the outcome of the study". This conclusion is speculative, at best.

A 12-hour light/dark cycle was reportedly maintained with artificial lighting presumably not exceeding 200-ft candles. Access to the laboratory was restricted to personnel conducting the test.

Procedures

All rats used in the study were reportedly acclimated to test conditions for 7 days prior to the actual testing. Page 8 of the report indicates that a commercial rodent diet was provided, along with water *ad-libitum* from "an automatic water system". Water provided in bowls or other "open cup" type waterers (including those which are automatic or gravity-fed) are specifically recommended against by EPA's Protocols due to their higher potential to become fouled, spilled, or nested-in by rodents.

The test group consisted of 10 males and 10 females. The amount of each food provided to rats during the pre-test holding and test period was not stated explicitly in the narrative portion of the report. However, the specific amounts provided during the test period can be determined in the "food and bait consumption" data provided on

pages 17-23 and the amounts provided during the pre-test holding period can be at least assumed based upon the "PROTOCOL FOR STUDY" document appended to the back of the report.[26] Based upon this document, it appears that a laboratory diet (PMI Feeds, Inc. Formulab #5008) was provided *ad libitum* during the pre-test holding period.

For the first day of testing, about 40 grams of the test material was provided per cage per day alongside about 40 grams of the EPA Challenge Diet. Based upon the application materials submitted to EPA in support of registration, 40 grams would be supplied through the use of 2 placepacks. For the control group, 10 males and ten 10 females were reportedly maintained concurrently with the test group. The control group was given about 40 grams of the EPA Challenge Diet per day in a single container for the duration of the test period (7 days in this case).[27] Collection and replenishment of the challenge diet for control rats was presumably done exactly as was done for the test rats. To minimize the effects of feeding preference for test rats, the two substances were reportedly reversed between days 1 and 2 (the bait exposure period).[28] Information about how the bait was presented (i.e., whether it was provided within its placepack wrapping) was lacking in the report. However, the report refers to the test material simply provided as "bait", so it must be assumed that whole packs were provided to the rats. To measure the amount of each feeding substance eaten by the rats, each day the

> Food was recovered and weighed to establish exact food consumption data. The gross weight of bait and/or challenge diet feed give, remaining from the previous study day, and consumed between feedings was determined daily and all consumed feed returned to approximate starting weight by the addition of bait or challenge diet.

No mention is made regarding the handling of chewed (or whole) placepack material. The test substance was reportedly removed after 2 days of choice feeding, with EPA Challenge Diet being continued for the remaining 5 days, or until death. For control rats, EPA Challenge Diet was provided for the entire 7-day period.

Testing was presumably completed on 03/03/15. After death, each rat was to be collected and weighed immediately upon death. Any surviving test rats and all control rats were to be weighed at the end of the test period.

Results

Within the 7 days of testing, 19 of the 20 test-group rats died (95% mortality) and none of the control-group rats died (0% mortality). This meets the Protocol 1.209 criteria of at least 90% mortality for the test rats, and not greater than 10% mortality for control rats.
Of
Days to death for test rats are provided in the following table.

	Day							
	0	1	2	3	4	5	6	7
No. Dead	0	0	0	17	19	19	19	19

[26] It would be far preferable for Stillmeadow to clearly state up front what procedures were actually done rather than leaving the reader to assume that the appended "PROTOCOL FOR STUDY" procedures were actually performed.
[27] As Stillmeadow was reportedly able to achieve the minimum mortality criterion within 5 days of post-exposure monitoring, they likely decided that extending this period similarly to the mouse test was unnecessary.
[28] Assuming that test subjects had not already removed any of the placepacks from the food container and moved them to some other location within the enclosure.

All 20 of the test rats, and 7 of 20 control rats lost weight during the testing period. Test rat observations recorded on p. 24-26 of the report indicated only "decreased activity-slight" and "decreased activity-moderate" as pre-morbid symptoms for the mortalities. For the survivor, "decreased activity-slight" was initially recorded for days 4-5 of the study, but was followed up with "observation present" on days from days 6-7. This result is consistent with the survivor having consumed a toxic dose of the bait, but then having eventually recovered. Control rat observations only included "NOA", or no observable abnormalities and "light-colored feces".

Composite bait consumption values for test rats are provided in the following table.

	Bait Consumed (g)	Challenge Diet Consumed (g)	Percent Bait Acceptance
male	280.1	291.9	48.9%
female	214.3	198.4	51.9%
combined	494.4	490.3	50.2%

Bait acceptance for the test rats was 50.2%. Acceptance by female rats (51.9%) was only slighter higher than that by males (48.9%). Acceptance by males increased slightly between the first (47.5%) and second (51.2%) days of the bait-exposure period, although the combined take of both diets declined from 348.4 g to 223.6 g. For females, Day-1 acceptance was 53.0% with 241.6 g of take of both diets combined; while Day-2 acceptance was 50.4% with 171.1 g of total calculated consumption. Curiously, the author of the report concluded on page 12 that "[there] appears to be an appetite suppression effect on the treated animals". This conclusion is based upon consumption data calculated from the post-exposure phase of the trial. Most test-groups rats had *died* by the 2nd day of post-exposure monitoring.

For the surviving test rat (male "1-M"), data entries for bait consumption indicate that very little of the test bait was consumed compared to the Challenge Diet and are consistent with that individual not having eaten enough of the test bait to get a lethal dose. During the 2-day bait-exposure period, "1-M" was recorded to have consumed 5.5 g of the cholecalciferol bait and 53.8 g of OPP diet for an acceptance score of 9.3%. Over the course of the 5-day post-exposure monitoring period, this rat's calculated consumption of challenge diet ranged from little or none to 14.0 g. "1-M" reportedly lost 70.0 g from the day before the bait-exposure period began until the end of the bioassay.

Certificate of Analysis – EPA Challenge Diet and Test Bait

Analyses of the "BAS 410 06 I" batch #SXE05714/06 for percent cholecalciferol was provided on page 7 of 35 of the report. Results indicate 0.0702% and 0.0704% cholecalciferol. A separate analysis was performed for the EPA Challenge Diet, with results "below the limit of quantification" of 0.00001006 and 0.00001148% for both tested batches.

Formulation of EPA Challenge Diet and Test Bait

The specific batches of EPA Challenge Diet identified in this report were "Lot #S9021115" and "Lot #S9022615" and information regarding its ingredients and its creation was provided on p. 9 and 11 of the report. Based upon the expiration date of "Aug15" provided in the report and information regarding its ingredients, it appears that the criteria prescribed in Protocol 1.209 regarding EPA Challenge Diet are met.[29]

Formulation data for the test bait were not submitted with the original application package. However, these data were requested by EPA and were received and routed for review on 07/20/16. Two separate batch sheets

[29] As EPA Challenge Diet is semi-perishable, it is required that it either be used immediately upon preparation or stored in such a way that its palatability is not compromised prior to its later use.

for "batch #SXE05714/06" were provided, with one raw batch sheet dated 10/27/14 listing the bulk of the ingredients, and another computer-generated table providing additional information. A comparison of these data to the proposed CSFs dated 03/30/16 indicates that the tested batch matches the proposed Basic CSF. All of the proposed Alternate CSFs do not match the tested batch. As EPA has no data for these untested formulas, data generated for batch #SXE05714/06 will not support any of the proposed alternate formulations.

CONCLUSIONS and RECOMMENDATIONS

Aside from relative humidity straying beyond the Protocol 1.209 requirement, the most important detail omitted from this study was information regarding how diet/spillage was handled with regard to the actual placepack wrapping.

For the reasons previously discussed for the mouse test, Protocol 1.209 is not an appropriate method to determine bait acceptance for placepack baits. However, this trial does seem to indicate rat willingness to chew into the provided placepacks. Additionally, the prescribed mortality criterion of ≥ 90% was also met. **With some reservation, this study can be accepted to establish the placepack penetration portion of the efficacy requirement with regard to rats (i.e., what would be met by conducting a test in accordance with EPA Protocol 1.217 of the rat efficacy data requirement.)**

Note that the consumption of a sub-lethal amount of bait and the apparent recovery of one individual that occurred in this trial underscores the mistake of euthanizing moribund animals in rodenticide efficacy tests.

Doig, A. (2016) BAS 410 06 I: Acute Toxicity Unwrapped Bait Study in Rats. Project Number: 19163/15, 2015/7006446. Unpublished study prepared by Stillmeadow, Inc. 36p.

MRID# 49667519

This report describes a laboratory feeding trial purportedly conducted in accordance with EPA Protocol 1.209, a method for testing acute dry baits for efficacy against Norway rats (and for establishing "single-feeding" claims for second-generation anticoagulants if a single bait exposure day is used). Aside from the bait having been provided "unwrapped", this study appears to have been conducted similarly to the rat study assigned MRID# 49667518l.

Animal Care and Maintenance

For the testing, 40 Norway rats (Wistar strain) were reportedly used, with 19 males and 21 females. 10 rats of each sex comprised the test group, and 9 males and 11 females comprised the control group. At the start of the study (day -1) the male weight average was 278.4 and 274.3 grams, for control and test rats, respectively. The females were 230.1 and 228.4 grams for control and test rats, respectively. The average weight difference t between the sexes was reportedly 48.3 grams for control rats, and 45.9 grams for test rats. This maximum average difference between the sexes falls within the Protocol criterion of 65 grams.

According to the study report, rats were single-housed in 45 x 40 x 20 cm (17.7 x 15.7 x 7.9 in) "stainless steel suspended cages" with solid bottoms, which provides a bottom surface area of about 1,800 cm^2 (1.94 ft^2). This cage size meets the minimum 0.538-2.15 ft^2 criterion prescribed in Protocol 1.209 for single-housed rats.

No information regarding the temperature and relative humidity readings that occurred in the test room was provided aside from the entries "Actual Temp – 20-26°C" and "Rel. Humidity – 37-98%" on page 8 of the report. Raw data entries for temperature and relative humidity bracketing the test period should be supplied to provide information about how these figures were reached. Taken at face value, the relative humidity in the test

room strayed in both directions from that prescribed by Protocol 1.209 (50-55%). Without citing relevant data, the author explains this (and other) deviations from protocol on page 12 of the report by stating that "the deviations listed did not adversely affect the outcome of the study". This conclusion is speculative, at best.

A 12-hour light/dark cycle was reportedly maintained with artificial lighting presumably not exceeding 200-ft candles. Access to the laboratory was restricted to personnel conducting the test.

Procedures

All rats used in the study were reportedly acclimated to test conditions for 7 days prior to the actual testing. Page 8 of the report indicates that a commercial rodent diet was provided, along with water *ad-libitum* from "water bowls". Water provided in bowls or other "open cup" type waterers (including those which are automatic or gravity-fed) are specifically recommended against by EPA's Protocols due to their higher potential to become fouled, spilled, or nested-in by mice.

The test group consisted of 10 males and 10 females. The amount of each food provided to rats during the pre-test holding and test period was not stated explicitly in the narrative portion of the report. However, the specific amounts provided during the test period can be determined in the "food and bait consumption" data provided on pages 19-25 and the amounts provided during the pre-test holding period can be at least assumed based upon the "PROTOCOL FOR STUDY" document appended to the back of the report.[30] Based upon this document, it appears that a laboratory diet (PMI Feeds, Inc. Formulab #5008) was provided *ad libitum* during the pre-test holding period.

For the first day of testing, about 40 grams of the test material was provided per cage per day alongside about 40 grams of the EPA Challenge Diet. For the control group, 9 males and ten 11 females were reportedly maintained concurrently with the test group. The control group was given about 40 grams of the EPA Challenge Diet per day in a single container for the duration of the test period (7 days in this case). Collection and replenishment of the challenge diet for control rats was presumably done exactly as was done for the test rats. To minimize the effects of feeding preference for test rats, the two substances were reportedly reversed between days 1 and 2 (the bait exposure period). Information about how the bait was presented was provided on page 10 of the report. Apparently on day 0, the "bait packets for the test group were offered wrapped but were removed within 20 minutes, unwrapped, weighed and replaced in cages". This somewhat odd procedure was probably intended to be consistent with the idea of feeding the rats the bait "in the same form as it will be marketed". As EPA already has separate protocols for assessing placepack penetration and palatability/lethality of unwrapped placepacks, this procedure was unnecessary.[31] To measure the amount of each feeding substance eaten by the rats, each day the

> gross weight of each container and its contents was determined daily and returned to the starting weight by the addition of bait or challenge diet. Weighing accuracy was to the nearest 0.5 gram. If food became fouled by urine or feces, the food was replaced in each container. The quantity of each substance consumed by the rats during the preceding 24 hours was recorded daily. Spilled food was recovered and weighed to establish exact food consumption data. If food spillage was damp, it was dried to approximately its original moisture content before weighing.

[30] It would be far preferable for Stillmeadow to clearly state up front what procedures were actually done rather than leaving the reader to assume that the appended "PROTOCOL FOR STUDY" procedures were actually performed.

[31] According to Protocol 1.209, bait is to be presented in the same form as it is to be applied according to its label. It is unclear whether this additional disturbance on the first bait exposure day had any net effect on the feeding trial.

The test substance was reportedly removed after 2 days of choice feeding, with EPA Challenge Diet being continued for the remaining 5 days, or until death. For control rats, EPA Challenge Diet was provided for the entire 7-day period.

Testing was presumably completed on 07/27/15. After death, each rat was to be collected and weighed immediately upon discovery. Any surviving test rats and all control rats were to be weighed at the end of the test period.

Results

Within the 7 days of testing, 17 of the 20 test rats died (85% mortality) and none of the control mice died (0% mortality). This did not meet the Protocol 1.209 criterion of at least 90% mortality for the test rats, though it met the criterion of not greater than 10% mortality for control rats.

Days to death for test rats are provided in the following table.

	Day							
	0	1	2	3	4	5	6	7
No. Dead	0	0	0	7	14	17	17	17

Of the 20 test-group rats, 16 lost weight during the testing period. For control-group rats, 2 of 20 lost weight during over the same period. Test-group rat observations reported on p. 26 of the report indicated "activity decrease - slight", activity decrease – moderate", "piloerection" and "thin" as pre-morbid symptoms for the mortalities. For the 3 survivors (2 females and 1 male), "piloerection" was noted for 2, and "no observable abnormalities" was noted for the 3rd. This result is consistent with 2 survivors having consumed a toxic dose of the bait, but then having eventually recovered. Control rat observations only included "no observable abnormalities".

Composite bait consumption values for test rats are provided in the following table.

	Bait Consumed (g)	Challenge Diet Consumed (g)	Percent Bait Acceptance
male	102.7	258.5	28.4%
female	162.9	141.4	53.5%
combined	265.6	399.9	39.9%

Reported bait acceptance for the test rats was 39.9%. Acceptance by female rats (53.5%) was higher than that by males (28.4%). For the surviving test rats, data entries for bait consumption indicate that very little of the test bait was consumed by those individuals compared to the Challenge Diet, indicating that they did not care for the flavor of the bait. One problem that seems to have occurred in this particular trial is the reporting of negative consumption values on the 2nd day of bait exposure. As rats cannot vomit, this is an impossible result. With this having been said, the reported consumption figures have to be considered as at least somewhat inaccurate. Female "21-F" survived the trial and reportedly was asymptomatic after consuming -0.1 g of toxic bait and 27.3 g of challenge diet over the 2-day bait-exposure period. The two survivors that showed some evidence of poisoning, male "11-M" and female "36-F" were recorded to have consumed, respectively, 0.3 g and 3.1 g of the toxic bait.

Certificate of Analysis – EPA Challenge Diet and Test Bait

Analyses of the "BAS 410 06 I" batch #SXE05714/06 for percent cholecalciferol was provided on page 7 of the report. The analyses for this particular study were performed by a German laboratory (Institut Kuhlmann) using the FPV-64 analytical method. Results from this laboratory indicated 0.0809% cholecalciferol. A separate analysis for percent cholecalciferol in the EPA Challenge Diet (batch #S9071715) was apparently not performed or provided based upon the "Not provided to testing facility" note on page 7.[32]

Formulation of EPA Challenge Diet and Test Bait

The specific batch of EPA Challenge Diet identified in this report was "Lot #S9071715" and information regarding its ingredients and its creation was provided on p. 8-9 of the report. Aside from a lack of an analysis of the Challenge Diet for percent cholecalciferol, information provided in the report indicate that its creation and handling were otherwise appropriate.

CONCLUSIONS and RECOMMENDATIONS

This study is rejected for failure to achieve the minimum mortality criterion of ≥ 90% and for apparent problems regarding weigh-backs, and for not providing an analysis of EPA Challenge Diet for percent cholecalciferol. Due to these problems, there would seem to be little point in attempting to rehabilitate this study by supplying raw data and formulation information.

Note that the consumption of sub-lethal amounts of bait and the apparent recovery of some individuals that occurred in this trial underscores the mistake of euthanizing moribund animals in rodenticide efficacy tests.

Richter, D. (2016) BAS 410 06 I Soft Block: Norway Rat Acute Dry Bait Laboratory Test Method (OPP 1.209). Project Number: ASF/15/009, 2015/7006444. Unpublished study prepared by BASF Corporation. 47p.

MRID# 49667524

This report describes a laboratory feeding trial purportedly conducted in accordance with EPA Protocol 1.209, a method for testing acute dry baits for efficacy against Norway rats (and for establishing "single-feeding" claims for second-generation anticoagulants if a single bait exposure day is used). This appears to be a "repeat" of the study submitted as MRID# 49667519.

Animal Care and Maintenance

For the testing, 40 Norway rats (Wistar strain) were reportedly used with a 50:50 sex ration. 10 rats of each sex comprised both the test and control groups. At the start of the study (day -1) the male weight average was 311.8 and 316.8 grams, for control-group and test-group rats, respectively. The females were 234.5 and 241.1 grams for control and test rats, respectively. The average weight difference t between the sexes was reportedly 76.5 grams. This maximum average difference between the sexes falls outside of the Protocol criterion of 65 grams.

According to the study report, rats were single-housed in 40 x 25 x 20 cm (15.7 x 9.8 x 7.9 in) Polypropylene cages with "stainless-steel wire mesh" lids and bases, over a tray with a paper liner. This provides a bottom surface area of about 1,000 cm^2 (1.08 ft^2). This cage size meets the minimum 0.538-2.15 ft^2 criterion prescribed in Protocol 1.209 for single-housed rats, but not the prescribed "screen-bottom all-metal cages designed to hold laboratory rats".

[32] It is unclear why this analysis was not performed, as it is a requirement specified by EPA's Protocols and is also noted as a requirement on page 8 of Stillmeadow's own PROTOCOL FOR STUDY document. No explanation is provided under "Protocol Deviations" on page 12 of the report.

Daily recordings of temperature and relative humidity readings that occurred in the test room were provided on pages 40-41, though the (apparently computer-generated) reports are difficult to read. However, the entries "Actual Temp – 21-22°C" and "Rel. Humidity – 20-61%" were provided on page 9 of the report. This relative humidity range strayed from that prescribed by Protocol 1.209 (50-55%). Without citing relevant data, the author explains this (and other) deviations from protocol on page 37 of the report by stating that "the listed deviations did not adversely affect the study". This conclusion is considered speculative.

A 12-hour light/dark cycle was reportedly maintained, and access to the laboratory was restricted to personnel conducting the test.

Procedures

All rats used in the study were reportedly acclimated to test conditions for 10 days prior to the actual testing. Page 9 of the report indicates that a commercial rodent diet ("Hoveler Mause-und Rattenfutter") was provided *ad-libitum*, along with water *ad-libitum* from "water bottles". On the last pre-test holding day (Day -1), rats were provided with exactly 50.0 grams of the laboratory diet, which was then "weighed back" to quantify food consumption immediately prior to the 2-day bait exposure period.

The test group consisted of 10 males and 10 females. For the 2-day bait exposure period, "at least 50.0 g of bait and 50.0 g standard EPA Challenge Diet per animal per day were made available in separate containers within each cage". For the control group, 10 males and ten 10 females were reportedly maintained concurrently with the test group. The control group was given about 50 grams of the EPA Challenge Diet per day in a single container for the entire 12-day test period (2 days of bait exposure; 10 days post-exposure monitoring).[33] To minimize the effects of feeding preference for test rats, the two substances were reportedly reversed between days 1 and 2 (the bait exposure period). Information about how the bait was presented was provided on page 12 of the report. To measure the amount of each feeding substance eaten by the rats, each day the

> Food was recovered and weighed to establish exact food consumption data. Any spilled bait or challenge diet was retrieved from the filter paper underneath each cage and added to the appropriate container; fecal material was removed. No contents of the containers was spoiled by urine during the course of the trial. The gross weight of bait and/or challenge diet feed given, remaining from the previous study day, and consumed between feedings was weighed to the nearest 0.1 g daily and all consumed feed returned to approximate starting weight by the addition of bait or challenge diet.

The test substance was reportedly removed after 2 days of choice feeding, with EPA Challenge Diet being continued for the remaining 10 days, or until death. For control rats, EPA Challenge Diet was provided for the entire 12-day period.

Testing was presumably completed on 10/13/15. After death, each rat was to be collected and weighed immediately upon death. Any surviving test rats and all control rats were to be weighed at the end of the test period.

Results

[33] This test differed from the one conducted by Stillmeadow (MRID# 49667519) in that the post-exposure monitoring was extended from 5 days to 10 days. Though not necessary in this trial as the mortality criterion was reached within 4 days of post-exposure monitoring, this was clearly intended to allow additional time for test rats to die based upon the poor results apparent from the Stillmeadow study.

Within the 12 days of testing, 19 of the 20 test-group rats died (95% mortality) and none of the control-group rats died (0% mortality). This meets the Protocol 1.209 criterion of at least 90% mortality in the test group, and not greater than 10% mortality for control group.

Days to death for test-group rats are provided in the following table.

	Day												
	0	1	2	3	4	5	6	7	8	9	10	11	12
No. Dead	0	0	2	11	18	19	19	19	19	19	19	19	19

Of the 20 test-group rats, 19 lost weight during the testing period. For control-group rats, 7 of 20 lost weight during the same period. Test-group observations recorded on p. 28 of the report indicated "piloerection", "hunched posture" and "decreased activity" for 16, 13 and 10 of the 19 pre-morbid rats respectively. For the single, male survivor, "piloerection" was noted for post-exposure days 3-6, with "no abnormalities observable" recorded thereafter. This result is consistent with the survivor having consumed a toxic dose of the bait, but then having eventually recovered. Control rat observations only included "no abnormalities observable".

Composite bait consumption values for test rats are provided in the following table.

	Bait Consumed (g)	Challenge Diet Consumed (g)	Percent Bait Acceptance
male	132.1	376.9	25.9%
female	244.5	132.9	64.8%
combined	376.6	509.8	42.5%

Reported bait acceptance for the test rats was 42.5%. Consistent with the Stillmeadow trial, acceptance by female rats (64.8%) was higher than that by males (25.9%). For the surviving test male (21-M), data entries for bait consumption indicate that very little of the test bait was consumed by that individual (4.0 grams of bait, total, during the 2-day bait-exposure period, during which time "21-M" reportedly consumed 70.1 g of challenge diet). However, test male 29-M also consumed only 4.0 grams of test bait over the same period, but with an apparently lethal result. In any case, it seems that female rats accepted this bait better than males. For both sexes, bait acceptance and total consumption decreased somewhat over the course of the bait-exposure period. On the first day, males reportedly consumed 366.1 g of bait plus challenge diet and accepted the bait as 28.5% of total intake. On the second day, males consumed 142.9 of both diets combined and accepted the toxic bait at 19.3%. For females, Day-1 acceptance was 67.4% with 239.9 g of total intake. On Day 2, females accepted the bait at 60.1% and were calculated to have consumed 137.6 g of both diets combined.

Certificate of Analysis – EPA Challenge Diet and Test Bait

Two 2 analyses of the "BAS 410 06 I" batch #0014248520 for percent cholecalciferol were provided on pages 44-45 of the report. The analyses for this particular study were performed by a German laboratory (Institut Kuhlmann) using the "UHPLC-(QqQ)MS)" analytical method. Results from this laboratory indicated 0.07382 and 0.07394% cholecalciferol. Separate analyses for percent cholecalciferol in the EPA Challenge Diet (batches #15-01 and 15-02) were provided on pages 46-47 and indicated a concentration of $\leq$ 1.0 ppm (0.0001%) cholecalciferol for each.

Formulation of EPA Challenge Diet and Test Bait

The specific batches of EPA Challenge Diet identified in this report were "Lot #15-01 and 15-02" and information regarding the ingredients and creation of each was provided on pages 9-11 of the report. Taken at face value, the creation and handling of the EPA Challenge Diet were mostly appropriate. Note that Protocol

1.209 specifies that storage of Challenge Diet is to be "at -18°C or below until it is to be used". Page 32 of the report indicates that the Challenge Diet [will be] "maintained at -18 ± 5°C until used", which must be assumed to be non-guideline in the absence of data entries noting the specific freezer temperatures which occurred.[34]

Formulation data for the test bait were not submitted with the original application package. However, these data were requested by EPA and were received and routed for review on 07/20/16. Two separate batch sheets for "batch #0014248520" were provided, with one (undated) computer-generated table listing the bulk of the ingredients, and another computer-generated table providing some additional information. A comparison of these data to the proposed CSFs dated 03/30/16 indicates that the tested batch does not match *any* of the formulas proposed by BASF. As a result, efficacy data generated from this tested batch do not support any of the currently proposed formulations.

CONCLUSIONS and RECOMMENDATIONS

Despite the aforementioned problems, these data could be accepted to support palatability and lethality against rats (Protocol 1.209). However, the raw data submitted for the tested batch indicates that it clearly does not match the formulation proposed for registration. As a result, these data will not support registration of any of the currently proposed formulations.

Norway rat – Field trials

Bates, E. (2016) Field Trial Study on BAS 410 06 I Rodent Bait for the Control of the Norway Rat, Rattus norvegicus at Ken Probert Timber, Oswestry, Shropshire, England. Project Number: 9100, LR022/14/EPA, 2016/1001065. Unpublished study prepared by E.B. Trials. 41p.

MRID# 49667527

This study describes a field trial conducted on a 1.2-acre timber yard at "Ken Probert Timber, Oswestry, Shropshire, England" against Norway rats. The bait to be tested was identified as "BAS 410 06 I", which would appear to be the same bait proposed for EPA registration. Efficacy was to be determined using census baiting and tracking patch scores, which are common census methods for rodenticide field trials. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 4 days
Pre-treatment lag period: 10 days
Toxic bait exposure period (bait take; tracking patches): 7 days
Post-treatment lag period: 7 days
Post-treatment census period (census baiting; tracking patches): 4 days

For the pre-treatment census, 40 wooden bait trays (4.7 x 7 inches) containing 200 grams of whole wheat each were reportedly placed in locations throughout the study site. Bait take was then recorded over a 4-day period (pre-treatment census period) by weighing to the nearest 1.0 gram using an electronic balance. Trays were replenished with whole wheat daily during this 4-day period. The number of rats on the site was estimated by counting every 10 grams of whole wheat removed as being equal to 1 rat. As 625 grams of census bait (whole

[34] As EPA Challenge Diet is semi-perishable, it is required that it either be used immediately upon preparation or stored in such a way that its palatability is not compromised prior to its later use. No raw data entries were supplied indicating the specific freezer temperatures used to maintain the Challenge Diet.

wheat) reportedly were consumed as the maximum take that occurred during this period (on day 3), the researchers estimated that there were about 63 rats present on the site.

Marks on tracking patches were scored as:

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

Each day tracking scores for 38 tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were 4 x 8 inches each, and were reportedly freshly coated with powder immediately following all tracking measures. Tracking tiles were reportedly not placed at the same loci as were the census bait trays.

For the toxic bait exposure period, 36 bait trays each containing about 140 grams (8 bait units) were "laid in strategic, protected locations ca. 5-10 m (16-33 feet) apart throughout the infested areas". It is unclear whether these trays differed in appearance and/or size from the wooden trays used for the census baiting. The text "at no time were census [baits], tracking patches, or [toxic] bait placements located immediately adjacent to each other, except in confined places where close placement was necessary" indicates that effort was made to ensure that the census bait placements were as independent as possible from the subsequent toxic bait placements.[35] Diagrams appended to the report indicate *some* degree of "overlap" of census and toxic bait locations, though the 10-day lag period between census and toxic baiting probably mitigated some of the "conditioning" concerns to some degree. The 36 toxic bait points provided an initial bait placement of about 5 kg. Toxic bait was not replenished over the 7-day toxic bait exposure period. Tracking scores were calculated during the toxic bait exposure period, probably as a means of "checking" for tracking activity reductions coincident with toxic baiting.

Following a 7-day post-treatment lag period, post-treatment censuses were reportedly performed in the same manner and for the same number of days as was done for the pre-treatment censuses, except that only 100 g of census ration was used per tray rather than the 200 g per tray that was used for the pre-treatment census. Given the low post-treatment takes, this questionable change probably did not affect results much.[36] Trap-outs were apparently not performed following the post-treatment censuses.[37] Results obtained are presented in the following tables.

Pre-treatment Census	
Day	**Census Bait Take (grams)**
1	508
2	624
3	625
4	604

[35] If the same placement locations were used for the pre-treatment census bait (whole wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor or higher consumption than what might normally occur had the rats not been conditioned to those locations.
[36] If all census ration had been eaten during both census phases, however, the "result" would have been a 50% decrease in activity.
[37] Snap-trapping following post-treatment censuses is useful to measure residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

Post-treatment Census	
Day	Census Bait Take (grams)
1	0
2	13
3	37
4	40

Toxic Bait Exposure	
Day	Bait Take (grams)
1	896
2	29
3	0
4	0
5	0
6	0
7	0

Activity Index	Pre-treatment	Post-treatment	Percent Change
Census Baiting (max)	625 grams	40 grams	93.6%
Tracking Scores (max)	66	5	92.5%

Census bait take rose somewhat between the 1st and 2nd pre-treatment census days (508 to 624 grams), but leveled by day 4 (604 grams). Toxic Bait take was reportedly high on the first day of the toxic bait exposure period (896 grams), but fell sharply thereafter (to 0 grams by day 3). This is a common result of baiting with an acute toxicant.

Estimates of activity reduction in rats were high by both the census methods, with census baiting at a 93.6% reduction and tracking patches giving a 92.5% reduction. Note that these figures were calculated based upon the maximum score obtained for each census, and not the means.[38] Carcass searching during the post-treatment census revealed 2 dead rats, and no other non-targets. Observations of (live) non-targets present on the site included blackbirds, robins, a wren, and a chaffinch.

An analysis of the bait for percent cholecalciferol was provided on page 14 of the report, and results indicated 0.0777% cholecalciferol.

Formulation data for all of the ingredients and percentages in the test bait were not submitted with the original application package. However, these data were requested by EPA and were received and routed for review on 07/20/16. Two separate batch sheets for "batch #SXE05714/02" were provided, with one raw batch sheet dated 05/28/14 listing the bulk of the ingredients, and another computer-generated table providing additional information. A comparison of these data to the proposed CSFs dated 03/30/16 indicates that the tested batch matches the proposed Basic CSF. All of the proposed alternate CSFs do not match the tested batch. As EPA has no data for these untested formulas, data generated for batch #SXE05714/02 will not support any of the proposed alternate formulations.

Taken at face value, this field trial describes a successful (if not 100%) removal of Norway rats from a timber yard in England. As snap-trapping was not used at the conclusion of the post-treatment census, it is somewhat

[38] It is generally considered to be more accurate to use the maximum values for a given census versus means.

unclear whether any continued rat pressure existed at the study site that may have been captured by that method. In instances where snap trapping reveals >0.1 target rodents per trap night, data suggesting good control are brought into question.

Bates, E. (2016) Field Trial Study on BAS 410 05 I Rodent Bait for the Control of the Norway Rat, Rattus norvegicus at Frankton Grange Stud Farm, Ellesmere, Shropshire, England. Project Number: 8000, LR003/13/EPA, 2016/1001067. Unpublished study prepared by E.B. Trials. 41p.

MRID# 49667529

This study describes a field trial conducted on a 0.5 acre site identified as "Frankton Grange Stud Farm, Ellesmere, Shropshire, England" which apparently had an infestation of Norway rats. The bait to be tested was identified as "BAS 410 05 I", which would appear to differ from the bait proposed for EPA registration.[39] Efficacy was to be determined using census baiting and tracking patch scores, which are common census methods for rodenticide field trials. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 4 days
Pre-treatment lag period: 14 days
Toxic bait exposure period (bait take; tracking patches): 7 days
Post-treatment lag period: 5 days
Post-treatment census period (census baiting; tracking patches): 4 days

For the pre-treatment census, 40 wooden bait trays (4.7 x 7 inches) containing 200 grams of whole wheat each were reportedly placed in locations throughout the study site. Bait take was then recorded over a 4-day period (pre-treatment census period) by weighing to the nearest 1.0 gram using an electronic balance. Trays were replenished with whole wheat daily during this 4-day period. The number of rats on the site was estimated by counting every 10 grams of whole wheat removed as being equal to 1 rat. As 1504 grams of census bait (whole wheat) reportedly were consumed as the maximum take that occurred during this period (on day 4), the researchers estimated that there were about 150 rats present on the site.

Marks on tracking patches were scored as:

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

Each day tracking scores for 40 tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were 4 x 8 inches each, and were reportedly freshly coated with powder immediately following all tracking measures. Tracking tiles were reportedly not placed at the same loci as the census bait trays.

For the toxic bait exposure period, 39 bait trays each containing about 140 grams (8 bait units) were "laid in strategic, protected locations ca. 5-10 m (16-33 feet) apart throughout the infested areas". It is unclear whether these trays differed in appearance and/or size from the wooden trays used for the census baiting. The text "at no time were census [baits], tracking patches, or [toxic] bait placements located immediately adjacent to each

[39] The specific batch of this bait used must be provided and confirmed to be identical to BASF's proposed CSFs. According to MRID# 49667526, the formulation identified as "BAS 410 05 I" was developed for registration outside of the U.S.

other, except in confined places where close placement was necessary" indicates that effort was made to ensure that the census bait placements were as independent as possible from the subsequent toxic bait placements.[40] The 39 toxic bait points provided an initial bait placement of about 5.5 kg. Toxic bait was replenished between days 1 and 2 of the 7-day toxic bait exposure period, but was not replenished thereafter. Tracking scores were calculated during the toxic bait exposure period, probably as a means of "checking" for tracking activity reductions coincident with toxic baiting, similarly to how researchers may perform ground squirrel visual counts mid-treatment in field trials to determine whether the treatment is worth continuing to completion.

Following a 5-day post-treatment lag period, post-treatment censuses were reportedly performed in the same manner and for the same number of days as was done for the pre-treatment censuses. Trap-outs were apparently not performed following the post-treatment censuses.[41] Results obtained are presented in the following tables.

Pre-treatment Census	
Day	Census Bait Take (grams)
1	1149
2	929
3	1071
4	1504

Post-treatment Census	
Day	Census Bait Take (grams)
1	0
2	7
3	55
4	0

Toxic Bait Exposure	
Day	Bait Take (grams)
1	400
2	156
3	16
4	242
7	*13
*Take represents 3 days of bait exposure	

Activity Index	Pre-treatment	Post-treatment	Percent Change
Census Baiting (max)	1504 grams	55 grams	96.3%
Tracking Scores (max)	88	3	96.6%

Census bait take was moderate on the 1st pre-treatment census days (1149 grams), but then decreased on the 2nd day (929 grams) before rising through days 3 and 4 (1071 and 1504 grams, respectively). Toxic Bait take was

[40] If the same placement locations were used for the pre-treatment census bait (whole wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor of higher consumption than what might normally occur had the rats not been conditioned to those locations.

[41] Snap-trapping following post-treatment censuses is useful to measure residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

moderate on the first day of the toxic bait exposure period (400 grams), decreased on days 2 and 3, increased sharply again on day 4, and then seemed to taper off on days 5-7.

Estimates of activity reduction in rats were high by both the census methods, with census baiting at a 96.3% reduction and tracking patches giving a 96.6% reduction. Note that these figures were calculated based upon the maximum score obtained for each census, and not the means.[42] Carcass searching during the post-treatment census revealed no dead rats and no other non-targets. Observations of (live) non-targets present on the site included a buzzard, house sparrows, blackbirds, crows, robins, and chaffinches.

An analysis of the bait for percent cholecalciferol was provided on page 14 of the report, and results indicated 0.0803% cholecalciferol.

Taken at face value, this field trial describes a very successful (if not 100%) removal of Norway rats from a stud farm in England. As snap-trapping was not used at the conclusion of the post-treatment census, it is somewhat unclear whether any continued rat pressure existed at the study site that may have been captured by that method. In instances where snap trapping reveals >0.1 target rodents per trap night, data suggesting good control are brought into question. As the bait formula used for this trial is not the same as that proposed for registration with EPA, these data are of limited use for EPA registration.

Bates, E. (2016) Field Trial Study on BAS 410 05 I Rodent Bait for the Control of the Norway Rat, Rattus norvegicus, at New Crickett Farm, Ellesmere, Shropshire, England. Project Number: 2016/1001068, 8019, LR013/13/EPA. Unpublished study prepared by E.B. Trials. 44p.

MRID# 49667530

This study describes a field trial conducted on a 5 acre "rural agricultural site" at "New Crickett Farm, Ellesmere, Shropshire, England" which apparently had a mixed infestation of Norway rats and house mice. The bait to be tested was identified as "BAS 410 05 I", which would appear to differ from the bait proposed for EPA registration.[43] Efficacy was to be determined using census baiting and tracking patch scores, which are common census methods for rodenticide field trials. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 4 days
Pre-treatment lag period: 10 days
Toxic bait exposure period (bait take; tracking patches): 7 days
Post-treatment lag period: 7 days
Post-treatment census period (census baiting; tracking patches): 4 days

For the pre-treatment census, 49 wooden bait trays (4.7 x 7 inches) containing 200 grams of whole wheat each were reportedly placed in locations throughout the study site. Bait take was then recorded over a 4-day period (pre-treatment census period) by weighing to the nearest 1.0 gram using an electronic balance. Trays were replenished with whole wheat daily during this 4-day period. The number of rats on the site was estimated by counting every 10 grams of whole wheat removed as being equal to 1 rat. As 2271 grams of census bait (whole wheat) reportedly were consumed as the maximum take that occurred during this period (on day 4), the researchers estimated that there were about 227 rats present on the site.

Marks on tracking patches were scored as:

[42] It is generally considered to be more accurate to use the maximum values for a given census versus means.
[43] The specific batch of this bait used must be provided and confirmed to be identical to BASF's proposed CSFs. According to MRID# 49667526, the formulation identified as "BAS 410 05 I" was developed for registration outside of the U.S.

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

Each day tracking scores for 49 tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were 4 x 8 inches each, and were reportedly freshly coated with powder immediately following all tracking measures. Tracking tiles were reportedly not placed at the same loci as the census bait trays.

For the toxic bait exposure period, 56 bait trays each containing about 140 grams (8 bait units) were "laid in strategic, protected locations ca. 5-10 m (16-33 feet) apart throughout the infested areas". It is unclear whether these trays differed in appearance and/or size from the wooden trays used for the census baiting. The text "at no time were census [baits], tracking patches, or [toxic] bait placements located immediately adjacent to each other, except in confined places where close placement was necessary" indicates that effort was made to ensure that the census bait placements were as independent as possible from the subsequent toxic bait placements.[44] The 56 toxic bait points provided an initial bait placement of about 7.8 kg. Toxic bait was replenished between days 1 and 2 of the 7-day toxic bait exposure period, but was not replenished thereafter. Tracking scores were calculated during the toxic bait exposure period, probably as a means of "checking" for tracking activity reductions coincident with toxic baiting, similarly to how researchers may perform ground squirrel visual counts mid-treatment in field trials to determine whether the treatment is worth continuing to completion.

Following a 7-day post-treatment lag period, post-treatment censuses were reportedly performed in the same manner and for the same number of days as was done for the pre-treatment censuses. Trap-outs were apparently not performed following the post-treatment censuses.[45] Results obtained are presented in the following tables.

Pre-treatment Census	
Day	Census Bait Take (grams)
1	830
2	1342
3	1598
4	2271

Post-treatment Census	
Day	Census Bait Take (grams)
1	153
2	58
3	58
4	73

[44] If the same placement locations were used for the pre-treatment census bait (whole wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor of higher consumption than what might normally occur had the rats not been conditioned to those locations.

[45] Snap-trapping following post-treatment censuses is useful to measure residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

Toxic Bait Exposure	
Day	Bait Take (grams)
1	725
2	293
3	195
4	126
7	*574
*Take represents 3 days of bait exposure	

Activity Index	Pre-treatment	Post-treatment	Percent Change
Census Baiting (max)	2271 grams	153 grams	93.3%
Tracking Scores (max)	86	4	95.3%

Census bait take was moderate on the 1st pre-treatment census days (830 grams), but then increased over the next 3 days to 1342, 1598 and 2271 grams. Toxic Bait take was moderate on the first day of the toxic bait exposure period (725 grams), decreased on days 2-4, and then continued through days 5-7. The removal of an average of ~191 grams of bait per day for days 5-7 begs the question of whether the baiting period was ended too early.

Estimates of activity reduction in rats were high by both the census methods, with census baiting at a 93.3% reduction and tracking patches giving a 95.3% reduction. However, only half as much (100 g) of the census ration was used in each tray as the 200 g per tray that were used for the pre-treatment census. As half to all of the census bait placed was removed daily from trays 47 and 48 during the post-treatment census period, it is clear that failure to provide 200 g/tray for the post-treatment census biased the control estimate somewhat in favor of product performance.

Carcass searching during the post-treatment census revealed 1 dead rat and 15 dead "mice". No other dead non-targets were reportedly observed, leading the researcher to curiously conclude that "non-target wildlife therefore do not appear to be impacted by the bait treatment". This conclusion would only be true if effects to non-targets were always apparent, which seldom occurs in rodenticide field trials where researchers typically make brief, narrow searches for what are often wide-ranging animals. As a counterpoint, the researcher was apparently only able to gather evidence of rat mortality (i.e., bodies) for a *single rat* out of the roughly 200 which the censuses suggested (90% of 227 rats) during the post-treatment census period. The fact that 15 dead mice were located in the treatment area after baiting casts further doubt on this statement. Observations of (live) non-targets present on the site included a buzzard, house sparrows, blackbirds, a crow, robins, wrens, a woodpigeon, redwings, and a chaffinch.

An analysis of the bait for percent cholecalciferol was provided on page 14 of the report, and results indicated 0.0803% cholecalciferol.

Taken at face value, this field trial describes a very successful (if not 100%) removal of Norway rats from a rural agricultural site, though it is unclear how those figures were influenced by mice which were clearly present at the site. Though a single Norway rat will consume far more census bait than a mouse, the number of mouse carcasses located during post-treatment searching outnumbered rats 15:1. As snap-trapping was not used at the conclusion of the post-treatment census, it is somewhat unclear whether any continued rat pressure existed at the study site that may have been captured by that method. In instances where snap trapping reveals >0.1 target rodents per trap night, data suggesting good control are brought into question. As the bait formula used for this trial is not the same as that proposed for registration with EPA, these data are of limited use for EPA registration.

Bates, E. (2016) Field Trial Study on BAS 410 05 I Rodent Bait for the Control of the Norway Rat, Rattus norvegicus, at Ken Probert Timber, Oswestry, Shropshire, England. Project Number: 8025, LR028/13/EPA, 2016/1001069. Unpublished study prepared by E.B. Trials. 40p.

MRID# 49667531

This study describes a field trial conducted on a 1.2-acre timber yard at "Ken Probert Timber, Oswestry, Shropshire, England" against Norway rats. It appears that this particular trial occurred at the same site as the trial for MRID# 49667527, but differed in that this one occurred roughly a year earlier and used a different bait formula. The bait to be tested was identified as "BAS 410 05 I", which would appear to differ from the bait proposed for EPA registration.[46] Efficacy was to be determined using census baiting and tracking patch scores, which are common census methods for rodenticide field trials. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 4 days
Pre-treatment lag period: 10 days
Toxic bait exposure period (bait take; tracking patches): 7 days
Post-treatment lag period: 7 days
Post-treatment census period (census baiting; tracking patches): 4 days

For the pre-treatment census, 32 wooden bait trays (4.7 x 7 inches) containing 200 grams of whole wheat each were reportedly placed in locations throughout the study site. Bait take was then recorded over a 4-day period (pre-treatment census period) by weighing to the nearest 1.0 gram using an electronic balance. Trays were replenished with whole wheat daily during this 4-day period. The number of rats on the site was estimated by counting every 10 grams of whole wheat removed as being equal to 1 rat. As 656 grams of census bait (whole wheat) reportedly were consumed as the maximum take that occurred during this period (on day 1), the researchers estimated that there were about 58 rats present on the site.

Marks on tracking patches were scored as:

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

Each day tracking scores for 32 tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were 4 x 8 inches each, and were reportedly freshly coated with powder immediately following all tracking measures. Tracking tiles were reportedly not placed at the same loci as the census bait trays.

For the toxic bait exposure period, 36 bait trays each containing about 200 grams (11 bait units) were "laid in strategic, protected locations ca. 5-10 m (16-33 feet) apart throughout the infested areas". It is unclear whether these trays differed in appearance and/or size from the wooden trays used for the census baiting. The text "at no time were census [baits], tracking patches, or [toxic] bait placements located immediately adjacent to each other, except in confined places where close placement was necessary" indicates that effort was made to ensure

[46] The specific batch of this bait used must be provided and confirmed to be identical to BASF's proposed CSFs. According to MRID# 49667526, the formulation identified as "BAS 410 05 I" was developed for registration outside of the U.S.

that the census bait placements were as independent as possible from the subsequent toxic bait placements.[47] The 36 toxic bait points provided an initial bait placement of about 7.2 kg.[48] Toxic bait was replenished between days 1 and 2 of the 7-day toxic bait exposure period, but was not replenished thereafter. Tracking scores were calculated during the toxic bait exposure period, probably as a means of "checking" for tracking activity reductions coincident with toxic baiting, similarly to how researchers may perform ground squirrel visual counts mid-treatment in field trials to determine whether the treatment is worth continuing to completion.

Following a 7-day post-treatment lag period, post-treatment censuses were reportedly performed in the same manner and for the same number of days as was done for the pre-treatment censuses. Trap-outs were apparently not performed following the post-treatment censuses.[49] Results obtained are presented in the following tables.

Pre-treatment Census	
Day	Census Bait Take (grams)
1	656
2	647
3	465
4	555

Post-treatment Census	
Day	Census Bait Take (grams)
1	0
2	0
3	0
4	0

Toxic Bait Exposure	
Day	Bait Take (grams)
1	431
2	171
3	19
4	0
5	0
6	0
7	13

Activity Index	Pre-treatment	Post-treatment	Percent Change
Census Baiting (max)	656 grams	0 grams	100%
Tracking Scores (max)	58	0	100%

[47] If the same placement locations were used for the pre-treatment census bait (whole wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor of higher consumption than what might normally occur had the rats not been conditioned to those locations.

[48] 7.8 kg was the reported initial placement, but this appears to be an error.

[49] Snap-trapping following post-treatment censuses is useful to measure residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

Census bait take was moderate on the 1st pre-treatment census days (656 grams), then slightly decreased to 555 grams by the end of the pre-treatment census period. Toxic Bait take was moderate on the first day of the toxic bait exposure period (431 grams), decreased to 0 by day 4, with some slight take on day 7.

Estimates of activity reduction in rats were 100% by both the census methods. Carcass searching during the post-treatment census revealed 2 dead rats. No other dead non-targets were reportedly observed, leading the researcher to curiously conclude that "non-target wildlife therefore do not appear to be impacted by the bait treatment". This conclusion would only be true if effects to non-targets were readily apparent, which seldom occurs in rodenticide field trials where researchers typically make brief, narrow searches for what are often wide-ranging animals. Observations of (live) non-targets present on the site included crows, a house sparrow, robins, and a blackbird.

An analysis of the bait for percent cholecalciferol was provided on page 14 of the report, and results indicated 0.0803% cholecalciferol.

Taken at face value, this field trial describes a very successful removal of Norway rats from a timber yard in England. As snap-trapping was not used at the conclusion of the post-treatment census, it is somewhat unclear whether any continued rat pressure existed at the study site that may have been captured by that method. In instances where snap trapping reveals >0.1 target rodents per trap night, data suggesting good control are brought into question. As the bait formula used for this trial is not the same as that proposed for registration with EPA, these data are of limited use for EPA registration.

Bates, E. (2016) Field Trial Study on BAS 410 05 I Rodenticide Bait for the Control of the Norway Rat, Rattus norvegicus, at Park Mill Farm, Oswestry, Shropshire, England. Project Number: 15101, 2016/1001074. Unpublished study prepared by E.B. Trials. 47p.

MRID# 49667536

This study describes a field trial conducted at a rural agricultural site identified as "Park Mill Farm, Oswestry, Shropshire, England" against Norway rats. The bait to be tested was identified as "BAS 410 05 I", which would appear to differ from the bait proposed for EPA registration.[50] Efficacy was to be determined using census baiting and tracking patch scores, which are common census methods for rodenticide field trials. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 3 days
Pre-treatment lag period: 8 days
Toxic bait exposure period (bait take; tracking patches): 7 days
Post-treatment lag period: 7 days
Post-treatment census period (census baiting; tracking patches): 3 days

For the pre-treatment census, 81 wooden bait trays (4.7 x 7 inches) containing 200 grams of whole wheat each were reportedly placed in locations throughout the study site. Bait take was then recorded over a 3-day period (pre-treatment census period) by weighing to the nearest 1.0 gram using an electronic balance. Trays were replenished with whole wheat daily during this 3-day period. The number of rats on the site was estimated by counting every 10 grams of whole wheat removed as being equal to 1 rat. As 2967 grams of census bait (whole

[50] The formulation sheet for the specific batch of this bait used must be provided and confirmed to be identical to BASF's proposed CSFs. According to MRID# 49667526, the formulation identified as "BAS 410 05 I" was developed for registration outside of the U.S.

wheat) reportedly were consumed as the maximum take that occurred during this period (on day 3), the researchers estimated that there were about 297 rats present on the site.

Marks on tracking patches were scored as:

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

Each day tracking scores for 81 tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were 4 x 8 inches each, and were reportedly freshly coated with powder immediately following all tracking measures. Tracking tiles were reportedly not placed at the same loci as the census bait trays.

For the toxic bait exposure period, 63 bait trays each containing about 140 grams (8 bait units) were "laid in strategic, protected locations ca. 5-10 m (16-33 feet) apart throughout the infested areas". It is unclear whether these trays differed in appearance and/or size from the wooden trays used for the census baiting. The text "at no time were census [baits], tracking patches, or [toxic] bait placements located immediately adjacent to each other, except in confined places where close placement was necessary" indicates that effort was made to ensure that the census bait placements were as independent as possible from the subsequent toxic bait placements.[51] The 63 toxic bait points provided an initial bait placement of about 8.8 kg. Toxic bait was replenished between days 1 and 2 of the 7-day toxic bait exposure period, but was not replenished thereafter. Tracking scores were calculated during the toxic bait exposure period, probably as a means of "checking" for tracking activity reductions coincident with toxic baiting, similarly to how researchers may perform ground squirrel visual counts mid-treatment in field trials to determine whether the treatment is worth continuing to completion.

Following a 7-day post-treatment lag period, post-treatment censuses were reportedly performed in the same manner and for the same number of days as was done for the pre-treatment censuses. Trap-outs were apparently not performed following the post-treatment censuses.[52] Results obtained are presented in the following tables.

Pre-treatment Census	
Day	Census Bait Take (grams)
1	2026
2	2417
3	2967

Post-treatment Census	
Day	Census Bait Take (grams)
1	183
2	271
3	300

[51] If the same placement locations were used for the pre-treatment census bait (whole wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor of higher consumption than what might normally occur had the rats not been conditioned to those locations.

[52] Snap-trapping following post-treatment censuses is useful to measure residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

Toxic Bait Exposure	
Day	Bait Take (grams)
1	1811
2	731
3 through 7	368

Activity Index	Pre-treatment	Post-treatment	Percent Change
Census Baiting (max)	2967 grams	300 grams	89.9%
Tracking Scores (max)	155	17	89.1%

Census bait take was moderate on the 1st pre-treatment census days (2026 grams), increasing to 2967 grams by the 3rd day of the pre-treatment census period. Toxic Bait take was 1811 grams on the first day of the toxic bait exposure period, 731 grams on the 2nd day, and then totaled 368 grams on days 3 through 7.

Estimates of activity reduction in rats were 89.9% and 89.1% by census baiting and tracking scores, respectively. Carcass searching during the post-treatment census revealed 1 dead rat. No other dead non-targets were reportedly observed, leading the researcher to curiously conclude that "non-target wildlife therefore do not appear to be impacted by the bait treatment". This conclusion would only be true if effects to non-targets were readily apparent, which seldom occurs in rodenticide field trials where researchers typically make brief, narrow searches for what are often wide-ranging animals. Observations of (live) non-targets present on the site included crows, a house sparrow, robins, and a blackbird.

An analysis of the bait for percent cholecalciferol was provided on page 14 of the report, and results indicated 0.0781% cholecalciferol.

Taken at face value, this field trial describes a successful removal of Norway rats from a timber yard in England. As snap-trapping was not used at the conclusion of the post-treatment census, it is somewhat unclear whether any continued rat pressure existed at the study site that may have been captured by that method. In instances where snap trapping reveals >0.1 target rodents per trap night, data suggesting good control are brought into question. As the bait formula used for this trial is not the same as that proposed for registration with EPA, these data are of limited use for EPA registration.

Klemann, N. (2016) Field Trial Study on BAS 410 05 I Rodenticide Bait for the Control of the Norway Rat, Rattus norvegicus, at Witte Farm, Warendorf, Germany. Project Number: KLN/BASF/2013/2, 2016/1001075. Unpublished study prepared by Klemann. 27p.

MRID# 49667537

This study describes a field trial conducted at a rural agricultural site identified as "Witte Farm, Warendorf, Germany" against Norway rats. The bait to be tested was identified as "BAS 410 05 I", which would appear to differ from the bait proposed for EPA registration.[53] Efficacy was to be determined using census baiting and tracking patch scores, which are common census methods for rodenticide field trials. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 4 days

[53] The specific batch of this bait used must be provided to determine whether it conforms to any of BASF's proposed CSFs. According to MRID# 49667526, the formulation identified as "BAS 410 05 I" was developed for registration outside of the U.S.

Pre-treatment lag period: 10 days
Toxic bait exposure period (bait take; tracking patches): 21 days
Post-treatment lag period: 7 days
Post-treatment census period (census baiting; tracking patches): 4 days

For the pre-treatment census, 27 "bait boxes (Hentschke & Sawatzki, D-24506 Neumuenster, Germany)/plastic bait trays, and tracking patches" were placed throughout the study site. Each bait tray (within a "bait box"?) was provided 200 grams of whole wheat. Bait take was then recorded over a 4-day period (pre-treatment census period) by weighing to the nearest 1.0 gram using an electronic balance. Trays were replenished with whole wheat daily during this 3-day period. The number of rats on the site was estimated by counting every 10 grams of whole wheat removed as being equal to 1 rat. As 1607 grams of census bait (whole wheat) was reportedly consumed as the maximum take that occurred during this period (on day 4), the researchers estimated that there were about 161 rats present on the site.

Marks on tracking patches were scored as:

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

Each day tracking scores for 16 tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were about 5 x 5 inches each, and were reportedly freshly coated with powder immediately following all tracking measures. Tracking tiles were reportedly not placed at the same loci as the census bait trays.

For the toxic bait exposure period, 25 "bait boxes" each containing about 150 grams (8 bait units) were "laid in strategic, protected locations ca. 5-10 m (16-33 feet) apart throughout the infested areas". It is unclear whether the "bait boxes" used for the toxic bait were of the same design and size as those used for the pre-treatment census period.[54] The text "at no time were census [baits], tracking patches, or [toxic] bait placements located immediately adjacent to each other, except in confined places where close placement was necessary" indicates that effort was made to ensure that the census bait placements were as independent as possible from the subsequent toxic bait placements.[55] The 25 toxic bait points provided an initial bait placement of about 3.8 kg. Toxic bait was replenished for the first 4 days of the toxic bait exposure period, but was not replenished thereafter. Tracking scores were calculated during the toxic bait exposure period, probably as a means of "checking" for tracking activity reductions coincident with toxic baiting.

Following a 7-day post-treatment lag period, post-treatment censuses were reportedly performed in the same manner and for the same number of days as was done for the pre-treatment censuses. Trap-outs were apparently not performed following the post-treatment censuses.[56] Results obtained are presented in the following tables.

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[54] In the event that both bait stations were the same, the toxic bait consumption could have potentially been biased in favor of higher consumption than otherwise may have occurred, due to the rats having been conditioned to the stations during the pre-treatment census period.

[55] If the same placement locations were used for the pre-treatment census bait (whole wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor of higher consumption than what might normally occur had the rats not been conditioned to those locations.

[56] Snap-trapping following post-treatment censuses is useful to measure residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

Pre-treatment Census	
Day	Census Bait Take (grams)
1	1055
2	1405
3	1557
4	1607

Post-treatment Census	
Day	Census Bait Take (grams)
1	27
2	26
3	41
4	49

Toxic Bait Exposure	
Day	Bait Take (grams)
1	333
2	442
3	200
4	286
5 through 6	38
7 through 8	107
9 through 11	65
12 through 13	9
14 through 16	5
17 through 18	0
19 through 21	0

Activity Index	Pre-treatment	Post-treatment	Percent Change
Census Baiting (max)	1607 grams	49 grams	97.0%
Tracking Scores (max)	36	6	83.4%

Census bait take was 1055 grams on day 1, increasing to 1607 grams by the 4rd day of the pre-treatment census period. Toxic Bait take was 333 grams on the first day of the toxic bait exposure period, 442 grams on the 2nd day, and then only gradually decreased over the rest of the exposure period, reaching 0 by day 17.

Estimates of activity reduction in rats were 97.0% and 83.4% by census baiting and tracking scores, respectively. Note that these figures were calculated based upon the maximum score obtained for each census, and not the means.[57] The somewhat protracted toxic baiting period suggests that some rats were possibly reluctant to feed initially, or were hoarding or defending access to the bait, etc. during the 4-day pre-treatment census period. It is also possible that some number of rats were moving into the study site either at the end of the pre-treatment census period, or during the pre-treatment lag period and/or the heginning of the toxic baiting period. In either case, the somewhat extended 21-day baiting period seemed necessary in this trial to reach all of the rats which were present at the test site.

[57] It is generally considered to be more accurate to use the maximum values for a given census versus means.

Carcass searching during the post-treatment census revealed 8 dead rats. No dead non-targets were reportedly observed, leading the researcher to conclude that "non-target wildlife therefore do not appear to be impacted by the bait treatment". This conclusion would only be true if effects to non-targets were readily apparent, which seldom occurs in rodenticide field trials where researchers typically make brief, narrow searches for what are often wide-ranging animals. Observations of (live) non-targets present on the site were not noted in the report.

An analysis of the bait for percent cholecalciferol was provided on page 13 of the report, and results indicated 0.0803% cholecalciferol.

Taken at face value, this field trial describes a successful removal of Norway rats from an agricultural site in Germany. As snap-trapping was not used at the conclusion of the post-treatment census, it is somewhat unclear whether any continued rat pressure existed at the study site that may have been captured by that method. In instances where snap trapping reveals >0.1 target rodents per trap night, data suggesting good control are brought into question. Consumption data may have also been confounded to some degree if the same bait stations ("bait boxes") were used for the pre-treatment census baiting as were used for the subsequent toxic baiting. The report is not clear on this point. As the bait formula used for this trial is not the same as that proposed for registration with EPA, these data are of limited use for EPA registration.

House mouse – Field trials

Bates, E. (2016) Field Trial Study on BAS 410 06 I Rodent Bait for the Control of the House Mouse, Mus musculus domesticus, at Crickett Farm Food Store, Ellesmere, Shropshire, England. Project Number: 9144, LR021/14/EPA, 2016/1001066. Unpublished study prepared by E.B. Trials. 39p.

MRID# 49667528

This study describes a field trial conducted on a "rural agricultural site" at "Crickett Farm Food Store, Ellesmere, Shropshire, England" against house mice. The bait to be tested was identified as "BAS 410 06 I", which would appear to be the same bait proposed for EPA registration. Efficacy was to be determined using census baiting and tracking patch scores, similarly to the rat trial reviewed above. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 4 days
Pre-treatment lag period: 10 days
Toxic bait exposure period (bait take; tracking patches): 10 days
Post-treatment lag period: 7 days
Post-treatment census period (census baiting; tracking patches): 4 days

For the pre-treatment census, 30 "Roguard mouse bait boxes (BASF Corporation)" containing 30 grams of whole wheat each were reportedly placed in locations throughout the study site. Bait take was then recorded over a 4-day period (pre-treatment census period) by weighing to the nearest 1.0 gram using an electronic balance. The BASF bait stations were replenished with whole wheat daily during this 4-day period. The number of mice on the site was estimated by counting every 2.5 grams of whole wheat removed as being equal to 1 house mouse. As 159 grams of census bait (whole wheat) was reportedly consumed as the maximum take that occurred during this period (on day 1), the researchers estimated that there were about 64 mice present on the site.

Marks on tracking patches were scored as:

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

Each day tracking scores for 30 tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were reportedly freshly coated with powder immediately following all tracking measures.

For the toxic bait exposure period, "Roguard® mouse bait boxes, each containing approximately 40 grams (2 bait units), were laid in strategic, protected locations ca. 1-2 m (3-6 feet) apart throughout the infested areas". The text "at no time were census [baits], tracking patches, or [toxic] bait placements located immediately adjacent to each other, except in confined places where close placement was necessary" indicates that effort was made to ensure that the census bait placements were as independent as possible from the toxic bait (and tracking patch) placements.[58] A total of 30 toxic bait points were reportedly used, providing an initial total bait placement of about 1.2 kg. Toxic bait was replenished between days 1 and 2 of the 10-day toxic bait exposure period, but was not replenished thereafter.

Following a 7-day post-treatment lag period, post-treatment censuses were reportedly performed in the same manner and for the same number of days as was done for the pre-treatment censuses. Trap-outs were apparently not performed following the post-treatment censuses.[59] Results obtained are presented in the following tables.

Pre-treatment Census	
Day	Census Bait Take (grams)
1	159
2	157
3	111
4	106

Post-treatment Census	
Day	Census Bait Take (grams)
1	2
2	9
3	10
4	13

[58] If the same placement locations were used for the pre-treatment census bait (whole wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor or higher consumption than what might normally occur had the mice not been conditioned to those locations. Using the same design of bait station, if not the very same units, for census baiting and toxic baiting would seem to have introduced a bias favoring product performance.

[59] Snap-trapping following post-treatment censuses is useful for measuring residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

Toxic Bait Exposure	
Day	Bait Take (grams)
1	41
2	10
3	10
4	0
8	*25
9	0
10	0
*Take represents 4 days of bait exposure	

Activity Index	Pre-treatment	Post-treatment	Percent Change
Census Baiting (max)	159 grams	13 grams	91.8%
Tracking Scores (max)	69	8	88.4%

Census bait take started at 159 grams on the 1st pre-treatment census day, and then decreased each day thereafter to 157, 111, and 106 grams by day 4. Toxic Bait take decreased between the 1st and 2nd pre-treatment census days (41 to 10 grams), decreased to 0 by day 4, but then bumped back up to 25 grams (~6 g/day) by day 8, before decreasing to 0 once again.[60]

Estimates of activity reduction in house mice were high by both the census baiting (91.8%) and tracking patches (88.4%) measures. Note that these figures were calculated based upon the maximum score obtained for each census, and not the means.[61] Carcass searching during the testing revealed no dead mice or any other dead animals (i.e., non-targets), leading the researcher to somewhat ironically conclude that "non-target wildlife therefore do not appear to be impacted by the bait treatment". If a lack of observation of non-target bodies truly meant that no effects to non-targets were occurring, then the researcher's failure to locate any dead house mice could be equally taken to mean that house mice were not affected during the study. In reality, effects to non-targets by rodenticides containing cholecalciferol can and do occur, regardless of whether those effects are apparent during field research. Non-target species observed to be present on the site included blackbirds, a crow, a magpie, and wood pigeons.

An analysis of the bait for percent cholecalciferol was provided on page 14 of the report, and results indicated 0.0777% cholecalciferol.

Formulation data for all of the ingredients and percentages in the test bait were not submitted with the original application package. However, these data were requested by EPA and were received and routed for review on 07/20/16. Two separate batch sheets for "batch #SXE05714/02" were provided, with one raw batch sheet dated 05/28/14 listing the bulk of the ingredients, and another computer-generated table providing additional information. A comparison of these data to the proposed CSFs dated 03/30/16 indicates that the tested batch matches the proposed Basic CSF. All of the proposed alternate CSFs do not match the tested batch. As EPA has no data for these untested formulas, data generated for batch #SXE05714/02 will not support any of the proposed alternate formulations.

[60] This result may have been taken from house mice which had not located (or had not chosen to feed on) the bait until the first few days of toxic baiting had passed. Alternately, the take reported on day 8 may have been from some other species present at the test site. Post-treatment snap-trapping may have been useful to detect those species in the latter situation.

[61] It is generally considered to be more accurate to use the maximum values for a given census versus means.

Taken at face value, this field trial describes a successful (if not 100%) removal of house mice from a rural agricultural site in England. As snap-trapping was not used at the conclusion of the post-treatment census, it is somewhat unclear whether any continued mouse (or other rodent) pressure existed at the study site that may have been captured by that method. In instances where snap trapping reveals >0.1 target rodents per trap night, data suggesting good control are brought into question.

Bates, E. (2016) Field Trial Study on BAS 410 05 I Rodenticide Bait for the Control of the House Mouse, Mus musculus domesticus, at Days Reupholstery, Shropshire, England. Project Number: 8018, LR014/13/EPA, 2016/1001070. Unpublished study prepared by E.B. Trials. 43p.

MRID# 49667532

This study describes a field trial conducted on an "urban site" at a commercial workshop identified as "Days Reupholstery, Oswestry, Shropshire, England" against house mice. The bait to be tested was identified as "BAS 410 05 I", which would appear to differ from the bait proposed for EPA registration.[62] Efficacy was to be determined using census baiting and tracking patch scores. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 4 days
Pre-treatment lag period: 10 days
Toxic bait exposure period (bait take; tracking patches): 7 days
Post-treatment lag period: 7 days
Post-treatment census period (census baiting; tracking patches): 4 days

For the pre-treatment census, 47 wooden bait trays (75 x 90 mm/3 x 3.5 in) containing 30 grams of whole wheat each were reportedly placed in locations throughout the study site. Bait take was then recorded over a 4-day period (pre-treatment census period) by weighing to the nearest 1.0 gram using an electronic balance. The trays were replenished with whole wheat daily during this 4-day period. The number of mice on the site was estimated by counting every 2.5 grams of whole wheat removed as being equal to 1 house mouse. As 165 grams of census bait (whole wheat) was reportedly consumed as the maximum take that occurred during this period (on day 1), the researchers estimated that there were about 66 mice present on the site.

Marks on tracking patches were scored as:

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

Each day tracking scores for 47 tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were reportedly freshly coated with powder immediately following all tracking measures.

For the toxic bait exposure period, 47 bait points with "bait trays" each containing approximately 40 grams (2 bait units) were laid in "strategic, protected locations ca. 1-2 m (3-6 feet) apart throughout the infested areas". The text "at no time were census [baits], tracking patches, or [toxic] bait placements located immediately adjacent to each other, except in confined places where close placement was necessary" indicates that effort was

[62] The specific batch of this bait used must be provided and confirmed to be identical to BASF's proposed CSFs. According to MRID# 49667526, the formulation identified as "BAS 410 05 I" was developed for registration outside of the U.S.

made to ensure that the census bait placements were as independent as possible from the toxic bait (and tracking patch) placements.[63] The 47 bait points/trays provided an initial **total** bait placement of about 1.9 kg. Toxic bait was replenished between days 1 and 2 of the 7-day toxic bait exposure period, but was not replenished thereafter.

Following a 7-day post-treatment lag period, post-treatment censuses were reportedly performed in the same manner and for the same number of days as was done for the pre-treatment censuses. Trap-outs were apparently not performed following the post-treatment censuses.[64] Results obtained are presented in the following tables.

Pre-treatment Census	
Day	Census Bait Take (grams)
1	105
2	115
3	165
4	121

Post-treatment Census	
Day	Census Bait Take (grams)
1	30
2	19
3	14
4	22

Toxic Bait Exposure	
Day	Bait Take (grams)
1	110
2	19
3	0
4	0
5	0
6	0
7	0

Activity Index	Pre-treatment	Post-treatment	Percent Change
Census Baiting (max)	165 grams	30 grams	81.9%
Tracking Scores (max)	60	12	80%

Census bait take started at 105 grams on the 1st pre-treatment census day, and then increased to 165 on day 3, before decreasing slightly to 121 grams by day 4. Toxic Bait take decreased between the 1st and 2nd pre-treatment census days (110 to 19 grams), and decreased to 0 thereafter.

[63] If the same placement locations were used for the pre-treatment census bait (whole wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor or higher consumption than what might normally occur had the mice not been conditioned to those locations.

[64] Snap-trapping following post-treatment censuses is useful for measuring residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

Estimates of activity reduction in house mice were moderate by both the census baiting (81.9%) and tracking patches (80%) measures, exceeding EPA's rather lenient 70% criterion for field efficacy trials. Note that these figures were calculated based upon the maximum score obtained for each census, and not the means.[65] Bates attributes the lack of apparent complete control to invasions from unmanaged nearby sites, but the presence of residual activity with no bait take after day 2 suggests that there were some bait-shy survivors.

Carcass searching during the testing revealed no dead mice or any other dead animals (i.e., non-targets), leading the researcher to somewhat ironically conclude that "non-target wildlife therefore do not appear to be impacted by the bait treatment". If a lack of observation of non-target bodies truly meant that no effects to non-targets were occurring, then the researcher's failure to locate any dead house mice could be equally taken to mean that the baiting effort was entirely ineffective. In reality, effects to non-targets by rodenticides containing cholecalciferol can and do occur, regardless of whether those effects are apparent during field research. No non-target species were observed to be present "within 25m (82 feet)" of the test site.

An analysis of the bait for percent cholecalciferol was provided on page 14 of the report, and results indicated 0.0803% cholecalciferol.

Taken at face value, this field trial describes a moderately successful removal of house mice from an urban site in England. As snap-trapping was not used at the conclusion of the post-treatment census, it is somewhat unclear whether any continued mouse pressure existed at the study site that may have been captured by that method. In instances where snap trapping reveals >0.1 target rodents per trap night, data suggesting good control are brought into question. As the bait formula used for this trial is not the same as that proposed for registration with EPA, these data are of limited use for EPA registration.

Bates, E. (2016) Field Trial Study on BAS 410 05 I Rodenticide Bait for the Control of the House Mouse, Mus musculus domesticus, At Old Crickett Storage Units, Oswestry, Shropshire, England. Project Number: 9026, LR005/14/EPA, 2016/1001071. Unpublished study prepared by E.B. Trials. 47p.

MRID# 49667533

This study describes a field trial conducted on an "urban site" at a commercial facility identified as "Old Crickett Storage Units, Oswestry, Shropshire, England" against house mice. The bait to be tested was identified as "BAS 410 05 I", which would appear to differ from the bait proposed for EPA registration.[66] Efficacy was to be determined using census baiting and tracking patch scores. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 4 days
Pre-treatment lag period: 10 days
Toxic bait exposure period (bait take; tracking patches): 7 days
Post-treatment lag period: 7 days
Post-treatment census period (census baiting; tracking patches): 4 days

For the pre-treatment census, 68 wooden bait trays (75 x 90 mm/3 x 3.5 in) containing 30 grams of whole wheat each were reportedly placed in locations throughout the study site. Bait take was then recorded over a 4-day period (pre-treatment census period) by weighing to the nearest 1.0 gram using an electronic balance. The trays were replenished with whole wheat daily during this 4-day period. The number of mice on the site was estimated by counting every 2.5 grams of whole wheat removed as being equal to 1 house mouse. As 94 grams

[65] It is generally considered to be more accurate to use the maximum values for a given census versus means.
[66] The specific batch of this bait used must be provided and confirmed to be identical to BASF's proposed CSFs. According to MRID# 49667526, the formulation identified as "BAS 410 05 I" was developed for registration outside of the U.S.

of census bait (whole wheat) was reportedly consumed as the maximum take that occurred during this period (on day 1), the researchers estimated that there were about 36 mice present on the site.[67] The Report's claim of mean daily census-ration take of 127 g is way off and likely came from the report for the "piggeries" trial – MRID# 49667534.

Marks on tracking patches were scored as:

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

Each day tracking scores for 68 tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were reportedly freshly coated with powder immediately following all tracking measures.

For the toxic bait exposure period, 53 bait points with "bait trays" each containing approximately 40 grams (2 bait units) were laid in "strategic, protected locations ca. 1-2 m (3-6 feet) apart throughout the infested areas". The text "at no time were census [baits], tracking patches, or [toxic] bait placements located immediately adjacent to each other, except in confined places where close placement was necessary" indicates that effort was made to ensure that the census bait placements were as independent as possible from the toxic bait (and tracking patch) placements.[68] The 53 bait points/trays provided an initial total bait placement of about 2.1 kg. Toxic bait was replenished between days 1 and 2 of the 7-day toxic bait exposure period, but was not replenished thereafter.

Following a 7-day post-treatment lag period, post-treatment censuses were reportedly performed in the same manner and for the same number of days as was done for the pre-treatment censuses. Trap-outs were apparently not performed following the post-treatment censuses.[69] Results obtained are presented in the following tables.

Pre-treatment Census	
Day	**Census Bait Take (grams)**
1	88
2	88
3	93
4	94

[67] At 2.5 g/ mouse, 37 or 38 would have probably been the "correct" number.
[68] If the same placement locations were used for the pre-treatment census bait (whole wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor or higher consumption than what might normally occur had the mice not been conditioned to those locations.
[69] Snap-trapping following post-treatment censuses is useful for measuring residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

Post-treatment Census	
Day	Census Bait Take (grams)
1	0
2	0
3	0
4	0

Toxic Bait Exposure	
Day	Bait Take (grams)
1	22
2	82
3	29
4	0
5	0
6	2
7	0

Activity Index	Pre-treatment	Post-treatment	Percent Change
Census Baiting (max)	94 grams	0 grams	100%
Tracking Scores (max)	96	3	96.9%

Census bait take started at 88 grams on the 1st pre-treatment census day, and then slightly increased to 94 grams by day 4. Toxic Bait take started at 22 grams on day 1, increased to 82 grams on day 2, and then decreased to 0 by day 4, with a small amount of removal occurring on day 6.

Estimates of activity reduction in house mice were 100% by census baiting, and high by the tracking patches (96.9%) measures. Carcass searching during the testing revealed no dead mice or any other dead animals (i.e., non-targets), leading the researcher to conclude that "non-target wildlife therefore do not appear to be impacted by the bait treatment". If a lack of observation of non-target bodies truly meant that no effects to non-targets were occurring, then the researcher's failure to locate any dead house mice could be equally taken to mean that the baiting effort was entirely ineffective. In reality, effects to non-targets by rodenticides containing cholecalciferol can and do occur, regardless of whether those effects are apparent during field research. Non-targets observed near the treatment site included house sparrows and a chaffinch.

An analysis of the bait for percent cholecalciferol was provided on page 14 of the report, and results indicated 0.0803% cholecalciferol.

Taken at face value, this field trial describes a very successful removal of house mice from an urban site in England. As snap-trapping was not used at the conclusion of the post-treatment census, it is somewhat unclear whether any continued mouse pressure existed at the study site that may have been captured by that method. In instances where snap trapping reveals >0.1 target rodents per trap night, data suggesting good control are brought into question. As the bait formula used for this trial is not the same as that proposed for registration with EPA, these data are of limited use for EPA registration.

Bates, E. (2016) Field Trial Study on BAS 410 05 I Rodenticide Bait for the Control of the House Mouse, Mus musculus domesticus, Inside the Old Piggeries at Pentredaffydd Farm, Oswestry, Shropshire, England. Project Number: 9011, LR006/14/EPA, 2016/1001072. Unpublished study prepared by E.B. Trials. 41p.

This study describes a field trial conducted on a rural, agricultural farm at the "old piggeries at Pentredaffydd Farm, Oswestry, Shropshire, England" against house mice. The bait to be tested was identified as "BAS 410 05 I", which would appear to differ from the bait proposed for EPA registration.[70] Efficacy was to be determined using census baiting and tracking patch scores. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 4 days
Pre-treatment lag period: 10 days
Toxic bait exposure period (bait take; tracking patches): 7 days
Post-treatment lag period: 7 days
Post-treatment census period (census baiting; tracking patches): 4 days

For the pre-treatment census, 38 wooden bait trays (75 x 90 mm/3 x 3.5 in) containing 30 grams of whole wheat each were reportedly placed in locations throughout the study site. Bait take was then recorded over a 4-day period (pre-treatment census period) by weighing to the nearest 1.0 gram using an electronic balance. The trays were replenished with whole wheat daily during this 4-day period. The number of mice on the site was estimated by counting every 2.5 grams of whole wheat removed as being equal to 1 house mouse. As 145 grams of census bait (whole wheat) was reportedly consumed as the maximum take that occurred during this period (on day 4), the researchers estimated that there were about 58 mice present on the site.

Marks on tracking patches were scored as:

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

Each day tracking scores for 38 tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were reportedly freshly coated with powder immediately following all tracking measures.

For the toxic bait exposure period, 43 bait points with "bait trays" each containing approximately 40 grams (2 bait units) were laid in "strategic, protected locations ca. 1-2 m (3-6 feet) apart throughout the infested areas". The text "at no time were census [baits], tracking patches, or [toxic] bait placements located immediately adjacent to each other, except in confined places where close placement was necessary" indicates that effort was made to ensure that the census bait placements were as independent as possible from the toxic bait (and tracking patch) placements.[71] The 43 bait points/trays provided an initial total bait placement of about 1.7 kg. Toxic bait was replenished between days 1 and 2 of the 7-day toxic bait exposure period, but was not replenished thereafter.

Following a 7-day post-treatment lag period, post-treatment censuses were reportedly performed in the same manner and for the same number of days as was done for the pre-treatment censuses. Trap-outs were

[70] The specific batch of this bait used must be provided and confirmed to be identical to BASF's proposed CSFs. According to MRID# 49667526, the formulation identified as "BAS 410 05 I" was developed for registration outside of the U.S.
[71] If the same placement locations were used for the pre-treatment census bait (whole wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor or higher consumption than what might normally occur had the mice not been conditioned to those locations.

apparently not performed following the post-treatment censuses.[72] Results obtained are presented in the following tables.

Pre-treatment Census	
Day	Census Bait Take (grams)
1	99
2	121
3	115
4	145

Post-treatment Census	
Day	Census Bait Take (grams)
1	10
2	6
3	9
4	11

Toxic Bait Exposure	
Day	Bait Take (grams)
1	135
2	20
3	27
4	0
5	10
6	0
7	4

Activity Index	Pre-treatment	Post-treatment	Percent Change
Census Baiting (max)	145 grams	11 grams	92.5%
Tracking Scores (max)	59	7	88.2%

Census bait take started at 99 grams on the 1st pre-treatment census day, and then increased to 145 grams by day 4. Toxic Bait take started at 135 grams on day 1, and then decreased sharply to 20 grams on day 2, stayed about the same on day 3 (27 grams), and then tapered off after that point.

Estimates of activity reduction in house mice were 92.5% by census baiting, and 88.2% by tracking scores. Note that these figures were calculated based upon the maximum score obtained for each census, and not the means.[73] Carcass searching during the testing revealed no dead mice or any other dead animals (i.e., non-targets), leading the researcher to somewhat ironically conclude that "non-target wildlife therefore do not appear to be impacted by the bait treatment". If a lack of observation of non-target bodies truly meant that no effects to non-targets were occurring, then the researcher's failure to locate any dead house mice could be equally taken to mean that the baiting effort was entirely ineffective. In reality, effects to non-targets by rodenticides containing cholecalciferol can and do occur, regardless of whether those effects are apparent during field research. Non-targets observed near the treatment site included house sparrows and a chaffinch.

[72] Snap-trapping following post-treatment censuses is useful for measuring residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

[73] It is generally considered to be more accurate to use the maximum values for a given census versus means.

An analysis of the bait for percent cholecalciferol was provided on page 14 of the report, and results indicated 0.0803% cholecalciferol.

Taken at face value, this field trial describes a successful removal of house mice from an agricultural site in England. As snap-trapping was not used at the conclusion of the post-treatment census, it is somewhat unclear whether any continued mouse pressure existed at the study site that may have been captured by that method. In instances where snap trapping reveals >0.1 target rodents per trap night, data suggesting good control are brought into question. As the bait formula used for this trial is not the same as that proposed for registration with EPA, these data are of limited use for EPA registration.

Bates, E. (2016) Field Trial Study on BAS 410 05 I Rodenticide Bait for the Control of the House Mouse, Mus musculus domesticus, in the Loft Areas at Pentredaffydd Farm, Oswestry, Shropshire, England. Project Number: 9101, LR014/14/EPA, 2016/1001073. Unpublished study prepared by E.B. Trials. 41p.

MRID# 49667535

This study describes a field trial conducted on a rural site identified as "loft areas at Pentredaffydd Farm, Oswestry, Shropshire, England" against house mice. The bait to be tested was identified as "BAS 410 05 I", which would appear to differ from the bait proposed for EPA registration.[74] Efficacy was to be determined using census baiting and tracking patch scores. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 4 days
Pre-treatment lag period: 10 days
Toxic bait exposure period (bait take; tracking patches): 9 days
Post-treatment lag period: 7 days
Post-treatment census period (census baiting; tracking patches): 4 days

For the pre-treatment census, 45 wooden bait trays (75 x 90 mm/3 x 3.5 in) containing 30 grams of whole wheat each were reportedly placed in locations throughout the study site. Bait take was then recorded over a 4-day period (pre-treatment census period) by weighing to the nearest 1.0 gram using an electronic balance. The trays were replenished with whole wheat daily during this 4-day period. The number of mice on the site was estimated by counting every 2.5 grams of whole wheat removed as being equal to 1 house mouse. As 277 grams of census bait (whole wheat) was reportedly consumed as the maximum take that occurred during this period (on day 1), the researchers estimated that there were about 110 mice present on the site.

Marks on tracking patches were scored as:

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

[74] The formulation sheet for the specific batch of this bait used must be provided and confirmed to be identical to BASF's proposed CSFs. According to MRID# 49667526, the formulation identified as "BAS 410 05 I" was developed for registration outside of the U.S.

Each day tracking scores for 45 tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were reportedly freshly coated with powder immediately following all tracking measures.

For the toxic bait exposure period, 57 bait points with "bait trays" each containing approximately 40 grams (2 bait units) were laid in "strategic, protected locations ca. 1-2 m (3-6 feet) apart throughout the infested areas". The text "at no time were census [baits], tracking patches, or [toxic] bait placements located immediately adjacent to each other, except in confined places where close placement was necessary" indicates that effort was made to ensure that the census bait placements were as independent as possible from the toxic bait (and tracking patch) placements.[75] The 57 bait points/trays provided an initial total bait placement of about 2.3 kg.[76] Toxic bait was inspected (but not replenished) on days 7 and 9 of the 9-day toxic bait exposure period.

Following a 7-day post-treatment lag period, post-treatment censuses were reportedly performed in the same manner and for the same number of days as was done for the pre-treatment censuses. Trap-outs were apparently not performed following the post-treatment censuses.[77] Results obtained are presented in the following tables.

Pre-treatment Census	
Day	Census Bait Take (grams)
1	277
2	210
3	256
4	271

Post-treatment Census	
Day	Census Bait Take (grams)
1	0
2	0
3	9
4	13

Toxic Bait Exposure	
Day	Bait Take (grams)
1 through 7	237
8 through 9	0

Activity Index	Pre-treatment	Post-treatment	Percent Change
Census Baiting (max)	277 grams	13 grams	95.3%
Tracking Scores (max)	69	0	100.0%

Census bait take was 277 grams on the 1st pre-treatment census day, and then decreased to 210 grams by day 2, before increasing to 256 g and 271 g on days 3 and 4, respectively. As toxic bait take was only measured on

[75] If the same placement locations were used for the pre-treatment census bait (whole wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor or higher consumption than what might normally occur had the mice not been conditioned to those locations.

[76] 2.5 kg was the reported initial placement, but this appears to be an error.

[77] Snap-trapping following post-treatment censuses is useful for measuring residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

day 7 and 9, it is unclear how much bait was removed on which days.[78] All that can really be said is that 237 grams of the bait were removed over the first 7 days, and nothing was removed during the last 2 days of the toxic bait exposure period.

Estimates of activity reduction in house mice were 95.3% by census baiting, and 100% by tracking scores. Carcass searching during the testing revealed no dead mice or any other dead animals (i.e., non-targets), leading the researcher to conclude that "non-target wildlife therefore do not appear to be impacted by the bait treatment". If a lack of observation of non-target bodies truly meant that no effects to non-targets were occurring, then the researcher's failure to locate any dead house mice could be equally taken to mean that the baiting effort was entirely ineffective. In reality, effects to non-targets by rodenticides containing cholecalciferol can and do occur, regardless of whether those effects are apparent during field research. Non-targets observed near the treatment site included house sparrows, blue tits, a robin, a woodpigeon, blackbirds, a coal tit, swifts, and swallows.

An analysis of the bait for percent cholecalciferol was provided on page 14 of the report, and results indicated 0.0803% cholecalciferol.

Taken at face value, this field trial describes a successful removal of house mice from a rural site in England. As snap-trapping was not used at the conclusion of the post-treatment census, it is somewhat unclear whether any continued mouse pressure existed at the study site that may have been captured by that method. In instances where snap trapping reveals >0.1 target rodents per trap night, data suggesting good control are brought into question. That some consumption of census bait was detected on the last 2 days of the post-treatment census period suggests that a few mice might have immigrated into the study area. As the bait formula used for this trial is not the same as that proposed for registration with EPA, these data are of limited use for EPA registration.

Riegel, C. (2016) Field Trial Study on BAS 410 06 I Rodent Bait for the Control of the House Mouse, Mus musculus domesticus, at three urban sites in New Orleans, LA. Project Number: 2016/7001336, R2016/BASF/01. Unpublished study prepared by City of New Orleans Mosquito, Termite and Rodent Control. 54p.

MRID# 49667538

This study describes a field trial conducted on three urban sites in New Orleans, LA against house mice. The 3 sites to be treated were described as an aquarium, a maintenance facility, and a police department warehouse. Details about the sites are provided in the following table.

[78] Additionally, page 10 of 41 of the report incorrectly lists "*R. norvegicus*" as the species responsible for toxic bait take.

Site	Description	Competing Food Sources
Aquarium	Complex structure with multiple indoor infestations in elevated planters container tropical foliage	Litter, food for exhibit animals
Turf facility	Simple slab foundation with many points of access from exterior	Grass seed, food scraps/trash
NOPD Warehouse	Simple slab foundation with multiple points of access from exterior	Narcotics, food scraps,trash

Oddly, "narcotics" was listed as a food source for house mice at the police department warehouse. If such things were indeed continually available to mice at this particular site, and as the effects of narcotics on mice are well-documented in the primary literature for affecting a wide range of functions, this site may have been inappropriate for rodenticide efficacy testing purposes.

The bait to be tested was identified as "BAS 410 06 I", which would appear to be the same bait proposed for EPA registration. Efficacy was to be determined using census baiting and tracking patch scores. The test design was as follows:

Pre-treatment census period (census baiting; tracking patches): 7 days (?)
Pre-treatment lag period: 7 days
Toxic bait exposure period (bait take; tracking patches): 14 days
Post-treatment lag period: 7 days
Post-treatment census period (census baiting; tracking patches): 7 days (?)

For the pre-treatment census, "bait trays" (15 cm in diameter) containing 50 grams of bulgur wheat each were reportedly placed in locations throughout the study sites. Census bait take was then recorded twice (on 12/08/15 and 12/14/15) by weighing to the nearest 1.0 gram using an electronic balance.[79] No other census bait measures reportedly occurred during this period. An estimation of the number of mice on the site was not provided by the researchers, but if the same calculation (2.5 g/mouse) as was used in the field studies by Bates that are discussed in this review is calculated from the maximum pre-treatment bait take values, rough estimates of 47, 42 and 15 mice for the aquarium, turf facility and police warehouse, respectively, might be used.

Marks on tracking patches were scored as:

0 = no tracks
1 = from 1 to 5 footprints
2 = from 6 footprints to 25% coverage of the patch
3 = from 25 to 95% coverage of the patch
4 = more than 95% coverage of the patch

[79] It is not clear how long the mice were exposed to the pre-treatment census bait, though it appears to have been about a 7-day period. It would have been preferable for at least 3 or more "readings" to have been taken during this period to determine any possible trends in census bait take and to get a more accurate estimate of how many mice were feeding.

Apparently on the same 2 days as pre-treatment census bait take was recorded (12/08/15 and 12/14/15), tracking scores for tracking patches were calculated and summed, providing pre-treatment tracking scores which could later be compared to post-treatment tracking scores. Patches were reportedly "shaken" immediately following all tracking measures, presumably to redistribute the disturbed sand appropriately. Though somewhat difficult to determine based upon the raw data appended to the report, it appears that the aquarium, turf facility (noted as "Parks & Parkways") and police warehouse had 20, 20 and 21 patches, respectively.[80]

For the 14-day toxic bait exposure period, totals of 16, 21 and 20 bait points with "bait boxes (Protecta Sidekick, Bell Laboratories)" each containing approximately 40 grams (2 bait units) were established in "specifically-selected" locations about 5-10 m (16-33 feet) apart throughout the infested areas for the aquarium, turf facility and police warehouse, respectively. The text "Census [baits], tracking patches, and [toxic] bait placements were not located immediately adjacent to each other except in confined/protected places where close placement was necessary" indicates that effort was made to ensure that the census bait placements were as independent as possible from the toxic bait (and tracking patch) placements.[81] Toxic bait was inspected and apparently replenished "every 48 to 96 hours, with no more than 96 hours between visits" over the baiting period.

Following a 7-day post-treatment lag period, post-treatment censuses were reportedly performed "one week later" (i.e., a single time for each of the 3 sites) after the post-treatment census bait was applied. The study director then averaged this single measurement over the elapsed days to obtain an average daily take. While taking a single post-treatment "reading" on the 7th post-treatment census day permits a maximum census take and tracking score to be calculated and compared to the pre-treatment figure, it does not accurately depict how the take actually occurred during the 7-day period.[82] Though the study director elected to record tracking patch marks by using daily averages, it is generally considered to be more accurate to use *maximum* values versus average measures in efficacy trials.[83] As no post-treatment raw data were submitted to permit a calculation of the maximum number of tracking patches marked for the police warehouse site, I have taken the value provided on page 10 of 54, assumed that it is accurate, and determined that about 7 patches were marked for this site on 01/19/16.

To permit a comparison of maximum values pre- and post-treatment, I have presented these figures in the tables below.

	Pre-treatment Census			Post-treatment Census		
Site	Day	Census Bait Take (grams)	Tracking Score	Day	Census Bait Take (grams)	Tracking Score
Aquarium	12/14/2015	106.3	32	1/19/2016	60.3	53
Turf Facility	12/14/2015	88.9	42	1/19/2016	1.1	7
Police Warehouse	12/14/2015	26.7	10	1/19/2016	10	7 (?)

[80] It seems highly unlikely that the low-contrast items provided as raw data sheets actually were the "best available copies". The originals of the forms almost certainly were white paper with black toner and ink.

[81] If the same placement locations were used for the pre-treatment census bait (bulgur wheat) and the toxic bait, it is possible that take of the toxic bait may have been biased in favor or higher consumption than what might normally occur had the mice not been conditioned to those locations.

[82] For example, if very little post-treatment census bait were removed for the first 6 days and then a larger amount was suddenly removed on day 7, it could at least be speculated that this late take may have resulted from immigration of mice (or other rodents) onto the study sites.

[83] No raw data were submitted to permit a calculation of the maximum number of tracking patches marked for the police warehouse site. These data should have appeared (at least chronologically) on page 35 of 54. Based upon the daily cumulative figure provided on page 11 of 54, it appears that 7 patches were marked for this site on 01/19/16.

Site	Cenus Bait Take Percent Change	Tracking Score Percent Change
Aquarium	43.3%	-65%
Turf Facility	98.8%	83.30%
Police Warehouse	62.6%	30%

Trap-outs were apparently not performed following the post-treatment censuses.[84]

Estimates of activity reduction in house mice were rather poor by both census methods for the aquarium and police warehouse sites. Estimates for the turf facility are consistent with successful control of a small population of house mice. Carcass searching during the testing revealed 1 dead mouse at the aquarium site, 7 dead mice at the police warehouse, and 10 dead mice at the turf facility. No non-target animals were found during the carcass searches, as indicated by the statement "the absence of affected non-target wildlife indicate that non-target organisms do not appear to be impacted by the treatment". In reality, effects to non-targets by rodenticides containing cholecalciferol can and do occur, regardless of whether those effects are apparent during field research. Non-targets observed near the treatment sites included various fish and macaws which were apparently able to "move freely" within the aquarium site during baiting. No non-targets were reportedly observed at the other 2 sites. Clearly, if any of the animals on display at the aquarium site were able to access the toxic bait, the baiting effort should have been discontinued immediately.

An analysis of the bait for percent cholecalciferol was provided on page 16 of the report, and results indicated 0.0777% cholecalciferol.

Formulation data for "batch #SXE05714/02" indicates that the tested batch matches the proposed Basic CSF. All of the proposed alternate CSFs do not match the tested batch. As EPA has no data for these untested formulas, data generated for batch #SXE05714/02 will not support any of the proposed alternate formulations.

Overall, this baiting effort must be judged to be a failure. Aside from a lack of efficacy, additional problems include some missing (and difficult to read) raw data and too few readings taken for the pre- and post-treatment census periods. Additionally, snap-trapping was not used at the conclusion of the post-treatment census, though residual mouse activity was obviously suggested by the post-treatment censuses at 2 of the 3 sites. Why the baiting effort was not continued in the face of continued mouse activity is also unclear.

Bait station performance data

Ward, R. (2009) Evaluation of the Enceladus Refillable Mouse Bait Station for Adult Opening, Refilling, and Reclosing Test for Reckitt Benckiser. Project Number: 1207/092. Unpublished study prepared by Perritt Laboratories, Inc. 21 p.

MRID# 47981701

This study was submitted to support EPA File Symbol 7969-GIG to fulfill Protocol 1.228, a bait station efficacy study designed to assess whether adult humans can perform the tasks needed to properly use a bait stations.

[84] Snap-trapping following post-treatment censuses is useful for measuring residual rodent activity, among other things. Occasionally, snap-trapping indicates continued rodent activity when other methods have indicated good control.

This study was previously submitted and reviewed (DP 375494) by the Agency in support of one of Reckitt Benckiser's products (EPA File Symbol 3282-RNE, which later became EPA Reg. No. 3282-102), and was found to be acceptable in an Agency review dated 08/26/10. It now appears that EPA File Symbol 7969-GIG is to share the same bait station with EPA Reg. No. 3282-102 (tier I designation). If the two stations are truly identical, the data requirement is met.

Ward, R. (2009) Evaluation of the Enceladus Refillable Mouse Bait Station for Unsecured Tamper-Resistant Test for Reckitt Benckiser. Project Number: 1207/091. Unpublished study prepared by Perritt Laboratories, Inc. 20 p.

MRID# 47981702

This study was submitted to support EPA File Symbol 7969-GIG to fulfill Protocol 1.229, the "child resistance" portion of the required bait station efficacy data. This study was previously submitted and reviewed (DP 375494) by the Agency in support of one of Reckitt Benckiser's products (EPA File Symbol 3282-RNE, which later became EPA Reg. No. 3282-102), and was found to be acceptable in an Agency review dated 08/26/10. If the two stations and use directions regarding loading the bait into the station are identical, these data will support the claim of resistance to tampering by children for EPA File Symbol 7969-GIG.

Watson, D. (2010) Weather Resistance of d-CON Bait Station XI. Unpublished study prepared by Reckitt Benckiser, Inc. 6 p.

MRID# 47981703

These data were submitted to support EPA File Symbol 7969-GIG to fulfill the "weather resistant" portion of the required bait station efficacy data for tier I stations. This study was previously submitted and reviewed (DP 375494) by the Agency in support of one of Reckitt Benckiser's products (EPA File Symbol 3282-RNE, which later became EPA Reg. No. 3282-102), and was found to be acceptable in an Agency review dated 08/26/10. If the two stations are identical, these data will support the claim of weather-resistance for EPA File Symbol 7969-GIG.

Dixon, L. (2009) The Evaluation of d-CON Bait Station XI Tamper Resistant to Dogs. Unpublished study prepared by Great Lakes Marketing Associates, Inc. 69 p.

MRID# 47981704

These data were submitted to support EPA File Symbol 7969-GIG to fulfill Protocol 1.230, the "dog resistant" portion of the bait station efficacy data. This study was previously submitted and reviewed (DP 375494) by the Agency in support of one of Reckitt Benckiser's products (EPA File Symbol 3282-RNE, which later became EPA Reg. No. 3282-102), and was found to be acceptable in an Agency review dated 08/26/10. If the two stations are identical, these data will continue to support a claim that the bait-station component of the product assigned EPA File Symbol 7969-GIG is resistant to tampering by dogs.

Ward, R. (2009) Evaluation of the Mimas Non-Refillable Mouse Bait Station for Unsecured Tamper-Resistant Test for Reckitt Benckiser. Project Number: 1207/082, 1/229/10/29/87. Unpublished study prepared by Perritt Laboratories, Inc. 18 p.

MRID# 47793801

This study was submitted to support the tier III designation for EPA File Symbol 7969-GIU to fulfill Protocol 1.229, the "child resistance" portion of the required bait station efficacy data. This study was previously submitted and reviewed (DP 369571) by the Agency in a review dated 12/16/09 to support of one of Reckitt Benckiser's products (EPA File Symbol 3282-OT, which later became EPA Reg. No. 3282-97). Note that this particular study was eventually "redone" when Reckitt wished to amend 3282-97 from a tier III bait station product to a tier I bait station product subsequent to its initial registration. As BASF has submitted this older study in support of EPA File Symbol 7969-GIU only, it appears that BASF wishes to use the *original* Reckitt tier III station for this particular product. These data were accepted back then and will support the claim of resistance to tampering by children for EPA File Symbol 7969-GIU, provided that the stations used in that product and in the cited study are truly identical.

BASF summary report

Hughes, S.; Keating, C. (2016) Selontra Rodent Bait: Efficacy, Secondary Toxicity, and Overall Data Understanding. Project Number: 2015/7006443. Unpublished study prepared by BASF plc. 147p.

MRID# 49667526

This 147 page report is primarily a narrative which touches on a wide range of rodenticide topics (mostly related to cholecalciferol), but probably the most important of which is at attempt to "explain" the results generated by BASF's proposed cholecalciferol bait in the laboratory and field efficacy data submitted in this application package.[85] To greatly summarize, BASF believes that EPA should overlook some of the poor results generated in the laboratory trials and instead consider various European field trials (reviewed below) together with the laboratory trials as a sort of "weight of the evidence" approach to EPA registration.

One of the first points made by BASF in this volume is the apparently better results obtained from the "wrapped bait" laboratory trials versus the trials using unwrapped bait. BASF argues that "the Selontra wrapper is designed to both allow odor from the bait to permeate and to provide an element of curiosity for the rodents, especially mice, which when feeding are accustomed to food being in some kind of wrapper". This conclusion seems quite speculative. Whether house mice are accustomed to food always being in "some kind of wrapper" is greatly dependent upon the treatment site and what food sources are available. It seems just as reasonable to speculate that "unwrapped" food items would be selected over "wrapped" foods, as "wrapped" food necessarily requires more energy expenditure for a mouse to obtain.[86]

Another point BASF attempts to make is that the poor results apparent in the house mouse tests, particularly regarding the numerous survivor males, can be attributed to "behavioral characteristics observed when male mice are caged in groups". It is worth mentioning here that group housing of mice is not mandated by EPA's Protocols, but is simply provided for as an option.[87] Further, the mouse lab test run by BASF's own laboratory (MRID 49667525) occurred nearly 7 months after the first Doig test (MRID 49667518) and about 2 months after the second Doig test (MRID 49667525), providing ample time for BASF to amend its laboratory protocols to employ single-housed mice for the third mouse study if it chose to do so. EPA has reviewed many, many laboratory trials for rodenticides (both anticoagulants and acute compounds) which utilized group-housed mice and in which EPA's applicable criteria for bait acceptance and mortality were met or exceeded.

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[85] Actually, this document deals with 2 separate baits – BAS 410 05 I and BAS 410 06 I. The former was apparently proposed for registration outside of the U.S., whereas the latter was created for U.S. EPA.

[86] It should also be noted that EPA has never noticed this sort of consumption discrepancy between the "wrapped" and "unwrapped" portions of the laboratory efficacy data required for mouse placepack products.

[87] EPA Protocol 1.210 states that mice may be housed individually or in single-sex groups of 5 of 10 mice per group.

BASF further argues that "the ultimate proof a rodenticide bait is efficacious against a target rodent pest species is successful field trials against those species, because field trials have death of the target rodent pest as the end point". There are a couple of problems with this statement. One, is that it is only true that death of the rodent is the endpoint if moribund target rodents are not *prematurely dispatched*, a situation alluded to in most (if not all) of the various "protocols for study" appended to BASF's laboratory and field trial reports. In cases where "poisoned" rodents are counted as "dead", mortality is not the endpoint. The other problem is that laboratory trials clearly also have death of the target rodent pest as the end point. Indeed, EPA's laboratory protocols specify a minimum mortality criterion which must be met for baits to be accepted. Field trials are generally considered to more closely resemble actual use conditions, but with the inherent disadvantage of the researchers not generally being able to directly account for each test subject's ultimate fate.[88] The advantage of laboratory tests is precisely the opposite; bait consumption can (at least theoretically) be measured accurately, and each test subject's fate is directly observable.

EPA has had rodenticide efficacy protocols in place for many years for the purpose of providing a set of easily-performed trials which provide for (what registrants continually refer to as) an "even playing field" for EPA to evaluate rodenticides. Baits which go through the battery of efficacy trials and achieve the prescribed performance criteria are registered, and those which do not meet those criteria are rejected. Whatever arguments are made to the contrary, it would be irresponsible for EPA to overlook poor results from rodenticide efficacy trials. Baits which are unpalatable or otherwise ineffective against the target rodents are likely to prolong public health threats and provide increased opportunity for bait to be available to non-target animals and/or move into the environment.

Efficacy data for rodenticide baits are formulation-specific as they must be eaten by the target species in order to be effective. Changes to registered rodenticide baits require new laboratory efficacy data demonstrating palatability and lethality against all claimed public health rodents. Newly proposed baits must be tested in efficacy trials using the identical formula to that which is proposed for registration.

CONCLUSIONS

Despite numerous methodological shortcomings, some lackluster results in a couple of the mouse laboratory trials, and a lack of snap-trapping following the post-treatment censuses in the field trials, these data will support registration of these 3 cholecalciferol products against rats and house mice. Specifically, the following MRIDs are accepted:

49667517 (rat laboratory penetration study)
49667518 (house mouse laboratory penetration study)
49667527 (rat field trial)
49667528 (house mouse field trial)

LABELING

The labels for EPA Reg. No. 7969-GIG and 7969-GIU contain some 5 pages of marketing claims, the majority of which are considered false and misleading. It was communicated to BASF that these claims (and the labeling in general) needed quite a bit of revision and that doing so may save both parties time during the review process. However, BASF apparently declined to do so. As a result, the remainder of this review will provide comment regarding the proposed claims.

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[88] In field trials, it is possible for test subjects to meet their demise in ways unrelated to the effects of the toxic bait alone (e.g., predation, exposure).

One of the groups of claims is somewhat ironically characterized by BASF's label as "Safety" claims, which EPA does not accept for any pesticide products. The list of claims below are all considered false and misleading.

Active Ingredient/Efficacy/Palatability

Very tasty/attractive to mice

This claim and any other claims about "high palatability" or "attractive" are not supported by the laboratory efficacy data, which indicated marginal palatability with regard to house mice.

Unique formulation/technology/formula

As EPA has registered baits containing cholecalciferol, this bait does not represent a "unique" formula or technology, although it could be true that no currently registered has a formulation that is identical to the basic formulation proposed for these products.

Deadly for mice

Though the efficacy data are consistent with this bait having killed some number of house mice, the claim "Deadly for mice" implies that this bait is particularly ideal (or better) for house mice. Based upon this interpretation and the existence of many data-supported rodenticide bait registrations, the claim is considered false and misleading.

Smell and taste attractive to mice

See the above response for "very tasty"

Fast results

The reported days-to-death results reviewed above are not consistent with this claim. As a result, the claim is considered false and misleading.

Mice love it to death

See above for "Deadly for mice"

Mice colony/infestation dies (controlled) in 1 week
Mice colony/infestation nibbles it to death in 1 week

None of these "colony control" claims are supported by the efficacy data. In some cases, the "colony" was not controlled at all, let alone in a single week. In any case, far too many factors influence whether an applicator will get control of a mouse population using a rodenticide bait for this claim to be supported for any rodenticide product.

Innovative bait

As this is neither the first cholecalciferol nor the first paste bait to be developed for registration, this statement is false and misleading.

Game-changing mouse control

There is nothing "game-changing" about this particular bait over any other baits. The game is the same (i.e., apply bait and hope for good results).

Mice stop feeding
Causes mice to lose their appetite after eating, which means they won't return to the bait to feed. This allows other less dominant mice to come out and feed

Though BASF clearly wishes to market some kind of "stop-feed" claim for this bait, the efficacy data do not support one. In the laboratory trials there was often much 2nd-day feeding. In some cases, the 2nd-day feeding more strongly favored the alternative diet than the bait, which is more consistent with bait shyness than an "anti-feedant /stop-feed effect". In the pen feeding trials using a different BASF bait containing cholecalciferol, there was often just as much (or nearly as much) feeding on the 1st day of bait exposure as there was during the pre-test period using the challenge diet. Thus, the data clearly demonstrate that there is no "stop-feed" effect for either of these baits. As a result, these claims are considered false and misleading.

Works from day 1
First kill/death on day 2
Mice start to die on day 1

As deaths did not occur in the laboratory trials until at least the 3rd day for every trial but one, a "dead rodents may begin appearing after 3 days" or some other iteration of this would be acceptable. Claims suggesting shorter times-to-death are not supported.

Solves your mice problem fast (quickly)

This claim is false and misleading. (See above)

Can kill large infestations in 1 week

This claim is false and misleading. Whether a rodenticide can kill *any* population of rodents in a specified, guaranteed period of time is dependent upon far too many factors for such a claim to be supported. As there were survivors and/or post-treatment consumption in several of the efficacy trials, these claims are not consistent with the efficacy data either.

First true bait alternative to anticoagulant rodenticides

This claim is false and misleading.

Problem-solving alternative to anticoagulants
Effective alternate to anticoagulants

This claim is false and misleading. Whether a rodenticide can "solve problems" is dependent upon far too many factors for such a claim to be supported. As there were survivors and post-treatment consumption in several of the efficacy trials, these claims are not consistent with the efficacy data either.

Ensures successful control of mice, including resistant strains

No bait can "ensure" anything with regard to success with a baiting operation. Some of the data reviewed above directly contradict someone "ensuring" control of mice. Thus, this claim is false and misleading.

Suitable for controlling resistant strains

(See above)

No fillers, all bait
More bait, less filler
Contains no [wax] filler

These claims are false and misleading, as all rodenticide baits contain food ingredients which could be considered "filler". Also, the first two claims contradict one another.

Discreet

The naked term "discreet" is unclear, but presumably it is meant to imply that the bait station is "unobtrusive" when placed as directed by the label. It could also be taken to mean that this particular bait station would be less noticeable than other similar bait stations. Whether either of these is actually the case depends seems unclear, thus the claim is considered false and misleading.

Station is big enough to fit [any/house] mouse

This claim is unclear, as the station obviously has to be large enough to accommodate a house mouse.

Contains bittering agent [to minimize risk to children]

The claim "contains Denatonium Benzoate" is acceptable, but EPA has rejected claims of safety related to bittering agents across the board for rodenticides. Therefore, the "to minimize risk to children" claim is false and misleading.

Achieved EPA's Maximum Protection Level

EPA has no "maximum protection level" for baits or bait stations. As a result, this claim is false and misleading.

NOT a nerve poison

This is an implied safety claim for this bait versus baits containing different active ingredients; EPA considers such claims to be false and misleading.

Low secondary risk to wildlife

This claim is an implied safety claim and is considered false and misleading.

Not an anticoagulant

This is a true statement clearly intended to give the misleading impression that rodenticide baits containing anticoagulants are less safe than baits containing other active ingredients. Although EPA authorizes registered pesticides to be used according to their labeling, EPA does not consider toxic pesticides to be safe and prohibits

making claims to that effect. Cholecalciferol is no different in that regard from other toxic rodenticides (i.e., it is considered a conventional chemical and not a reduced risk chemical). Thus, the claim is considered false and misleading per 40 CFR §156.10(a)(5)(iv) and (vii).

Treatment widely available [for pets]

This is a false statement.

New Bait Station New Child-Resistant [Bait] Station Design
New Design
New and Improved Bait Station

As BASF is clearly citing previously reviewed bait station resistance data from Reckitt, neither of the two proposed bait stations for these products is "new" or "improved" in any way. Therefore, these claims are considered false and misleading.

Labeling for Outer Carton Front, Back, or Side Panel Label

House mice cease feeding after consuming a toxic dose

See the comments above for *mice stop feeding.*

Hassle stops from day 1
No more trouble from day 1

These are not supported by the efficacy data, and would not be accepted for any rodenticide bait registered with EPA regardless. As a result, these are considered false and misleading.

Death process starts after feeding
Mice start to die after 1st feeding

See the above. comments

Very tasty flavor

See the above comment for "very tasty".

Wax-free

What BASF intends by this claim is unclear. EPA has several registered rodenticide baits containing wax (paraffin), which is used to help prevent spoilage of bait when used in wet or damp areas (e.g., sewers). Baits containing wax were originally thought unlikely to achieve the 33% bait acceptance criterion when used in trials with >3 days of bait exposure, but data EPA has reviewed since has indicated that wax blocks are accepted about as well as any other baits tested in the same manner. Therefore, the claim "wax free" is considered false and misleading per 40 CFR §156.10(a)(5)(iv) and (vii) as it seems to suggest that this bait will provide more favorable results than wax baits.